
The Misericordia Health Centre cataract comfort study

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ABSTRACT • RÉSUMÉ

Background: All surgery provokes various degrees of anxiety for patients. The environment leading up to surgery can affect anxiety levels. We performed a prospective randomized study to compare environmental factors around the time of cataract surgery in order to identify interventions that would minimize stress for patients.

Methods: Patients scheduled to undergo cataract surgery at a university-affiliated hospital in Winnipeg were randomly assigned to 1) receive orally administered lorazepam or a placebo before surgery; 2) listen to relaxing music through headphones or routine background noise before surgery; 3) walk (or go by wheelchair if unable to walk) to the operating room or go by stretcher; and 4) listen to relaxing music through headphones or routine background noise during surgery. Randomization for part 1 was double blind; for parts 2 and 3 the surgeon and anesthesiologist were blinded, but the patient was not. Patients were asked to rate their anxiety, sedation, nausea and pain on arrival at the preoperative area, about 30 minutes after arrival, on arrival in the operating room and on arrival in the postoperative area, on a visual analogue scale graded from 0 ("None" [or "Wide awake" in the case of sedation]) to 10 ("Worst possible" [or "Asleep" in the case of sedation]). Patient satisfaction and willingness to repeat the exact same form of treatment were also rated.

Results: Of the 19 surgeons in the department 18 agreed to participate; 1 withdrew during the study. Data were collected for 144 patients aged 26 to 93 years. Anxiety was highest on arrival at the institution and decreased progressively thereafter. Oral sedation and listening to music before surgery were associated with decreased anxiety and increased levels of sedation ($p = 0.002$). Walking to the operating room provided no benefit over going by stretcher. Listening to music through headphones during surgery was not accepted by many patients and, when used, negatively affected the surgeon's assessment of the patient's ability to cooperate. Surgeons reported movement more often among patients who received oral sedation than among those who did not ($\chi^2 = 0.01$). Levels of pain and nausea were extremely low in all patients, and satisfaction was very high. Patients who received regional local anesthesia had less pain and higher satisfaction than those who received topical anesthesia. Willingness to repeat the same treatment was extremely high.

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Interpretation: For patients undergoing cataract surgery, efforts should be directed toward reducing anxiety on arrival at the institution, when it is highest, and not just during surgery. Oral sedation and listening to music before surgery appear to be beneficial. Listening to music through headphones during surgery was not found to be advantageous.

Contexte : Toute chirurgie provoque une certaine anxiété chez les patients et l'ambiance qui prévaut avant l'opération peut en affecter le degré. Nous avons fait une étude prospective randomisée pour comparer les facteurs environnementaux lors d'une chirurgie de la cataracte et déterminer les genres d'intervention susceptibles de minimiser le stress chez les patients.

Méthodes : L'on a réparti au hasard en quatre groupes les patients qui devaient subir une chirurgie de la cataracte dans un hôpital universitaire de Winnipeg : 1) ceux qui recevraient par voie orale du lorazépam ou un placebo avant l'opération; 2) ceux qui écouterait de la musique relaxante sur écouteurs ou entendraient les bruits ambiants usuels avant la chirurgie; 3) ceux qui se rendraient à la salle d'opération en marchant (ou en fauteuil roulant si nécessaire) ou en civière; 4) ceux qui écouterait de la musique relaxante avec des écouteurs ou entendraient les bruits ambiants usuels pendant l'opération. La randomisation du premier groupe était à double insu; celles des 2^e et 3^e groupes étaient à simple insu, pour le chirurgien et l'anesthésiste seulement. On a demandé aux patients de coter leur degré d'anxiété, de sédation, de nausée et de douleur à leur arrivée dans la salle préopératoire, environ 30 minutes après leur arrivée, à l'arrivée dans la salle d'opération et à l'arrivée dans la salle postopératoire, et de l'indiquer sur une échelle analogique visuelle graduée de 0 («Aucune» [«Éveillé» pour les cas de sédation]) à 10 («Le pire» [«Endormi» pour les cas de sédation]). On a aussi coté la satisfaction des patients et leur désir de répéter exactement le même type de traitement.

Résultats : Parmi les 19 chirurgiens du département, 18 ont accepté de participer; un s'est retiré durant l'étude. Les données recueillies ont porté sur 144 patients, âgés de 26 à 93 ans. L'anxiété était à son plus haut degré à l'arrivée à l'institution, mais elle a diminué par la suite. On a associé la sédation par voie orale et l'écoute de la musique avant l'intervention à la baisse de l'anxiété et à la hausse du niveau de sédation ($p = 0,002$). La marche vers la salle d'opération n'a pas été plus bénéfique que le déplacement en civière. Plusieurs patients ont refusé d'écouter de la musique pendant l'opération et, chez ceux qui ont accepté, cela a réduit leur capacité de coopérer, selon les chirurgiens. Ceux-ci ont signalé des mouvements plus fréquents chez les patients qui avaient reçu une sédation par voie orale que les autres ($\chi^2 = 0,01$). Le niveau de douleur et de nausée a été extrêmement faible chez tous les patients et le degré de satisfaction, très élevé. Les patients qui ont reçu une anesthésie locale régionale ont moins souffert et étaient plus satisfaits que ceux qui avaient reçu une anesthésie topique. Le désir de recevoir de nouveau le même traitement a été très élevé.

Interprétation : Chez les patients qui subissent une chirurgie de la cataracte, on devrait s'efforcer de réduire l'anxiété à leur arrivée à l'institution alors qu'elle est à son plus haut degré, et non pas seulement pendant l'opération. La sédation par voie orale et l'écoute de la musique avant la chirurgie semblent être bénéfiques. L'écoute de la musique sur écouteurs pendant l'intervention ne s'est pas avérée bénéfique.

Patients who are about to undergo any surgical procedure routinely experience fear and apprehension. For cataract surgery this is often treated by ad-

ministering a sedative. At the Misericordia Health Centre, Winnipeg, our standard approach for years has been to give intravenously administered agents on the

patient's arrival at the operating room to relieve anxiety and induce mild sedation just before the local anesthetic block and the surgery. Recently it has been suggested that other interventions, such as music,¹ can also benefit patients. We carried out a prospective randomized controlled trial to identify interventions that may benefit patients undergoing cataract surgery in an outpatient setting under local anesthesia and to compare their relative influence.

METHODS

The study was performed between June 26 and July 20, 2000. Approval for the study was obtained from the Medicine Research Ethics Board of the University of Manitoba, Winnipeg. Patients were mailed a consent form 3 weeks before surgery. Patients who did not respond by mail were asked on arrival in the surgical holding area whether they wished to participate. The exclusion criteria consisted of age less than 18 years, deafness, cognitive impairment, language barrier, allergy to lorazepam or lactose, and inability to walk or sit in a wheelchair.

The patients were randomly assigned to 1) receive either orally administered lorazepam (0.5 mg for weight less than 50 kg, 1.0 mg for weight 50 kg or greater) or a placebo in the holding area before surgery; 2) listen to either relaxing music through headphones or routine background noise before surgery; 3) either walk (or go by wheelchair if unable to walk) to the operating room or go by stretcher; and 4) listen to either relaxing music through headphones or routine background noise during surgery. Patients assigned to listen to music were given a choice of classical, country, jazz or soft rock audiocassettes. Randomization for part 1 was double blind; for parts 2 and 3 the surgeon and anesthetist were blinded, but the patient was not. Randomization was not blinded for part 4 because it was evident to all whether headphones were in use.

A power calculation based on an estimated 5-point change in scores between the treatment arms and a 10-point standard deviation in scores indicated that at least 124 patients were required to achieve 80% power for an α of 0.05.

Patients were asked to rate their anxiety, sedation, nausea and pain on arrival at the preoperative area (time 1), about 30 minutes after arrival and oral administration of lorazepam or placebo (time 2), on arrival in the operating room (time 3) and on arrival in the post-operative area (time 4). The patients rated these variables on a visual analogue scale graded from 0 ("None"

[or "Wide awake" in the case of sedation]) to 10 ("Worst possible" [or "Asleep" in the case of sedation]). Just before discharge, patients were asked to rate their satisfaction with the overall experience on a visual analogue scale graded from 0 ("Not satisfied at all") to 100 ("Completely satisfied"). They were also asked to rate their willingness to repeat the exact same form of treatment for the other eye on a visual analogue scale graded from 0 ("Not willing to repeat") to 100 ("Completely willing to repeat"). Patients marked the scale themselves whenever possible; if poor vision precluded this, the patient was instructed to tell the nurse or study assistant what score to record.

At the end of surgery the surgeons were asked to grade the level of sedation (too light, appropriate or too heavy), whether they were satisfied with the patient's ability to cooperate during the procedure, and whether they encountered any problems with inappropriate movement.

All patients had blood pressure and heart rate monitoring before, during and after surgery, and pulse oximetry monitoring during surgery. We reviewed the anesthesia record after surgery to identify episodes of bradycardia (heart rate less than 60 beats per minute), tachycardia (heart rate more than 100 beats per minute), low blood oxygen saturation (less than 90%), diastolic deviation greater than 20 mm Hg from baseline or systolic deviation greater than 20 mm Hg from baseline, and any additional comments.

We analysed the visual analogue scale results as a multifactorial repeated-measures analysis of variance. χ^2 tests were done for associations between design factors and secondary outcomes and other possible concomitant factors. The significance level was set at $\alpha = 0.05$.

RESULTS

Of the 19 surgeons in the department 18 agreed to participate; during the study 1 surgeon withdrew. All seven anesthetists working during the study period participated. Data were collected for 144 patients, who ranged in age from 26 to 93 years. There was no statistically significant difference between the two arms for each independent variable with regard to sex, age, route of administration of anesthetic (topical versus injected [retro- or peribulbar]) or first-eye surgery except that patients who walked to the operating room were slightly younger than those who went by stretcher (mean age 68.8 years vs. 72.9 years) ($p = 0.028$), and a greater proportion of patients who were undergoing their second cataract procedure than those undergoing

their first cataract procedure received oral sedation (64.2% [34/53] vs. 38.4% [33/86]) ($p = 0.003$). The patients were originally assigned to 16 different groups representing all combinations of the four independent variables. During the study this pattern was broken after the first few days because of problems that arose with randomization to music during surgery. Twenty-four patients chose not to wear headphones during surgery, six failures of the music players occurred, and twice surgeons asked that the headphones not be used. We analysed the results based on the interventions received rather than intention to treat.

There was a statistically significant decrease in mean anxiety score between time 1 and time 2 (23.2 vs. 18.7) ($p = 0.023$) and between time 3 and time 4 (15.4 vs. 7.3) ($p < 0.001$) but not between time 2 and time 3 ($p = 0.094$) (Fig. 1). The subgroup with the highest mean anxiety score, 33.9, comprised those who did not listen to music preoperatively, received a placebo before surgery, walked to the operating room and listened to music intraoperatively. The two subgroups with the lowest mean anxiety scores were those who listened to music preoperatively, received lorazepam tablets, went to the operating room by stretcher and did not listen to music intraoperatively (mean score 6.5),

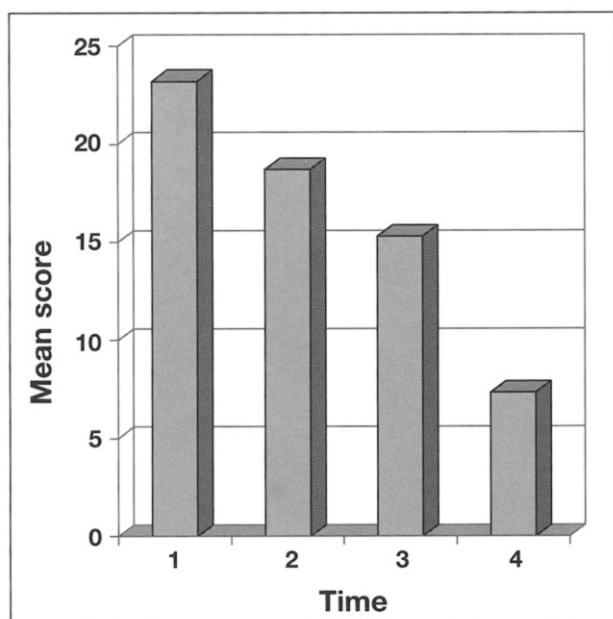


Fig. 1—Mean anxiety score (assessed on visual analogue scale from 0 ["None"] to 10 ["Worst possible"]) on arrival at pre-operative area (time 1), about 30 minutes after arrival and oral administration of lorazepam or placebo (time 2), on arrival in operating room (time 3) and on arrival in postoperative area (time 4) for patients undergoing cataract surgery.

and those who did not listen to music preoperatively, received lorazepam tablets, walked to the operating room and listened to music intraoperatively (6.0). These scores were significantly lower than that for the subgroup with the highest anxiety score ($p = 0.002$ and 0.006 respectively). At all four study times the mean anxiety score for patients who received topical anesthesia was slightly higher than the score for those who received injections of anesthetic, but these differences all failed to reach statistical significance.

The difference in mean sedation score was statistically significant between time 1 and time 2 (9.2 vs. 15.7) ($p = 0.013$), time 2 and time 3 (15.7 vs. 10.2) ($p = 0.035$), and time 3 and time 4 (10.2 vs. 26.7) ($p < 0.001$) (Fig. 2). At time 2, the subgroup with the highest sedation score comprised those who received orally administered lorazepam and listened to music preoperatively (mean score 27.4, compared with 9.5 for the subgroup who received placebo and listened to music preoperatively) ($p < 0.001$).

At all study times the mean nausea score was less than 1. The highest nausea score occurred at time 4 among the subgroup who received lorazepam tablets and went to the operating room by stretcher (mean score 2.9, compared with 0.07 for the subgroup who received lorazepam tablets and walked to the operating room) ($p = 0.004$).

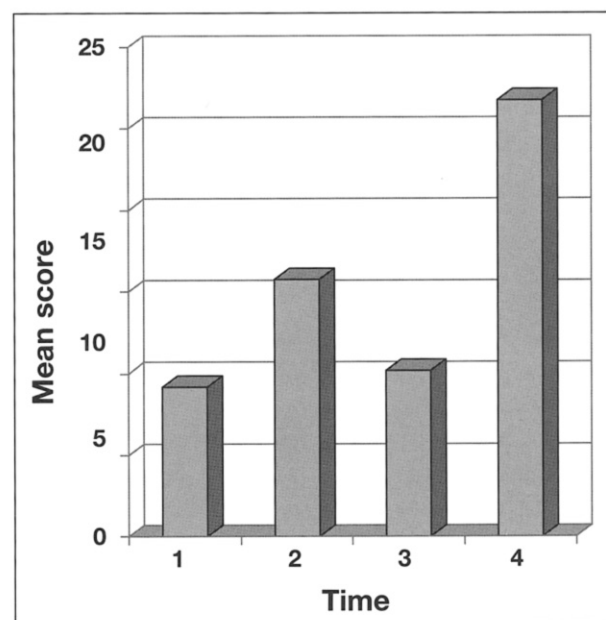


Fig. 2—Mean sedation score (assessed on visual analogue scale from 0 ["Wide awake"] to 10 ["Asleep"]) at the four study times.

The mean pain score was 3 or less at all four study times. Pain scores were not affected by the independent study variables but were affected by the type of anesthesia: at time 4 the subgroup who received topical anesthesia had a mean pain score of 7.1, compared with 1.5 for those who received regional local anesthesia ($p = 0.006$).

χ^2 testing showed no statistically significant difference in rates of bradycardia, tachycardia, hypotension or hypoxemia between the groups comparing the four independent variables. The only significant difference found in monitoring outcomes was a transiently higher rate of systolic hypertension among patients who walked to the operating room than among those who went by stretcher ($p = 0.02$). However, the hypertension was not felt to be clinically significant by the anesthesiologists and did not require any treatment.

The surgeon's assessment of the level of sedation did not correlate with listening to music preoperatively ($\chi^2 = 0.09$), transportation to the operating room ($\chi^2 = 0.64$) or listening to music during surgery ($\chi^2 = 1.37$) but did correlate with oral sedation ($\chi^2 = 0.01$). The surgeon's satisfaction with the patient's ability to cooperate during the procedure was not correlated with listening to music preoperatively ($\chi^2 = 0.81$), oral sedation ($\chi^2 = 0.20$), transportation to the operating room ($\chi^2 = 0.44$) or block type ($\chi^2 = 0.16$) but was negatively correlated with listening to music during surgery ($\chi^2 = 0.02$). Surgeons reported patient movement more often among patients who received orally administered lorazepam than among those who did not ($\chi^2 = 0.01$). One patient, who received oral sedation plus a regular dose of intravenously given sedative, made two sudden movements during surgery, one of which resulted in a tear in the posterior capsule. The surgeon felt that the patient was oversedated.

Overall patient satisfaction was extremely high (mean score 96.2). There was no statistically significant difference in patient ratings of satisfaction for any of the study independent variables. Patients who had regional local anesthesia had a significantly higher mean satisfaction score than those who had topical anesthesia (97.7 vs. 92.7) ($p = 0.008$). Patients' willingness to repeat the same treatment was extremely high, with 92% (128/139) assigning the highest score.

INTERPRETATION

Cataract surgery continues to evolve at a rapid rate.

Major changes have occurred in surgical technique and anesthesia in the last decade. The goal with each of these changes is to provide better-quality outcomes. In our study we chose variables that have been established to be associated with reduced anxiety for patients undergoing cataract surgery or other procedures under local anesthesia. In addition, we selected variables that we felt would be most acceptable to both surgeons and anesthesiologists. We felt that our institution provided an ideal setting to study interventions that could be applied in a broad range of settings because we have 19 surgeons and 8 anesthesiologists performing over 6600 cataract procedures per year.

Randomization was not as successful as we would have liked. More patients undergoing their second cataract procedure received oral sedation than those having first-eye surgery. It was expected that the former would be more relaxed because the experience was familiar to them and so they might have lower overall anxiety, skewing the results in favour of oral sedation. However, there was no significant difference in anxiety level on arrival at the preoperative area between these two groups, which suggests that the effect of prior experience was not large. Randomization also failed for listening to music during surgery because of patient, surgeon and technical reasons. Several surgeons indicated that they were not happy with patients' listening to music through headphones while they operated because of potential problems with communication.

The most significant finding of our study was that patient anxiety was greatest on arrival at the institution, not immediately before surgery. This pattern has been demonstrated in other studies,²⁻⁴ but its significance has not previously been stressed. Efforts toward alleviating anxiety, therefore, need to begin when the patient comes through the door or even before arrival. The combination of oral sedation and listening to relaxing music preoperatively appears to be beneficial in reducing this anxiety. However, too much sedation can lead to complications as a result of unexpected patient movement, as occurred in one case in our study.

We had expected that walking to the operating room would be associated with some reduction in patient anxiety, but we found it to have no identifiable effect. We selected this variable based on a study in which patients were asked after surgery to identify significant stressors.⁵ It may be that for elderly patients with cataract the stress induced from walking in an unfamiliar area after receiving eyedrops may

offset the loss of autonomy felt when wheeled on a stretcher.

The negative outcome we found related to listening to music through headphones intraoperatively was unexpected. Cruise and colleagues¹ reported that this can be associated with increased satisfaction during cataract surgery. It is possible that our problems with randomization for this variable may have created a selection bias. We wondered whether the type of anesthesia caused this discrepancy, because the surgeons who expressed the greatest displeasure with patients' wearing headphones were those who had converted in the previous year to using topical anesthesia. The negative correlation remained statistically significant, however, when the analysis was limited to patients who received injections of anesthetic.

We found that, compared with regional local anesthesia, topical anesthesia was associated with a non-significantly higher rate of anxiety around the time of surgery and with significantly higher pain scores after surgery and lower patient satisfaction scores. The finding of higher pain levels after topical anesthesia is consistent with a review article comparing topical versus regional anesthesia.⁶ Lower satisfaction among patients who received topical anesthesia was also noted by Katz and associates,⁷ whereas other investigators found no difference in ratings between the two groups.^{8,9}

Overall patient satisfaction and willingness to repeat the exact same treatment were high with all interventions. These findings are consistent with those of the only other study we were able to find comparing combinations of oral and intravenous sedation for cataract surgery¹⁰ and with studies assessing patient satisfaction with oral sedation alone.^{2,11–13}

All approaches in our study were found to be safe, with no sustained episodes of significant bradycardia, tachycardia, hypotension, hypertension or hypoxemia that required treatment.

The results from this study have led our hospital to begin work on a protocol for routine provision of music preoperatively and optional oral sedation on arrival for patients undergoing cataract surgery. In addition, studies examining methods of patient education days before surgery to reduce the initial anxiety on arrival are planned.

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