D. W. H. Lee[1]
A. C. W. Chan[1]
S. K. H. Wong[1]
T. M. K. Fung[1]
A. C. N. Li[1]
S. K. C. Chan[2]
L. M. Mui[1]
E. K. W. Ng[1]
S. C. S. Chung[1]

Can Visual Distraction Decrease the Dose of Patient-Controlled Sedation Required During Colonoscopy? A Prospective Randomized Controlled Trial

Background and Study Aims: We previously demonstrated that audio distraction using relaxation music could lead to a decrease in the dose of sedative medication required and improve patient satisfaction during colonoscopy. This prospective randomized controlled trial was designed to test the hypotheses that visual distraction may also decrease the requirement for sedatives and that audio and visual distraction may have additive beneficial effects when used in combination.

Patients and Methods: 165 consecutive patients who underwent elective colonoscopy were randomly allocated into three groups to receive different modes of sedation: group 1 received visual distraction and patient-controlled sedation (PCS); group 2 received audiovisual distraction and PCS; group 3 received PCS alone. A mixture of propofol and alfentanil, delivered by a Graseby 3300 PCA pump, was used for PCS in these groups. Each bolus of PCS delivered 4.8 mg propofol and 12 µg alfentanil. Measured outcomes included the dose of PCS used, complications, recovery time, pain score, satisfaction score, and willingness to use the same mode of sedation if the procedure were to be repeated.

Results: Eight patients were excluded after randomization. The mean±SD dose of propofol used in group 2 (0.81 mg/kg ± 0.49) was significantly less than the dose used in group 1 (1.17 mg/kg ± 0.81) and that used in group 3 (1.18 mg/kg ± 0.60) ($P < 0.01$, one-way analysis of variance). The mean ± SD pain score was also lower in group 2 (5.1 ± 2.5), compared with the pain scores in group 1 (6.2 ± 2.2) and group 3 (7.0 ± 2.4) ($P < 0.01$, one-way analysis of variance). The mean ± SD satisfaction score was higher in groups 1 (8.2 ± 2.4)) and 2 (8.4 ± 2.4), compared with the score in group 3 (6.1 ± 2.9) ($P < 0.01$, one-way analysis of variance). A majority of patients in groups 1 (73 %) and 2 (85 %) said that they would be willing to use the same mode of sedation again, compared with only 53 % in group 3 ($P < 0.01$, chi-squared test).

Conclusions: Visual distraction alone did not decrease the dose of sedative medication required for colonoscopy. When audio distraction was added, both the dose of sedative medication required and the pain score decreased significantly. Both visual and audiovisual distraction might improve patients' acceptance of colonoscopy.

Introduction

Anxiety and pain are common problems associated with colonoscopy and most endoscopy units prescribe some form of sedation for patients undergoing this procedure [1,2]. Although the use of sedation is both risky and costly [3–6], performing colonoscopy without sedation may adversely affect both the outcome and patients' tolerance and is therefore not universally accepted practice [7–9]. It is imperative that ways are found to reduce the use of sedation without affecting patients' tolerance and satisfaction. One possible solution is to use adjuvant therapy [9]. By using patient-controlled sedation (PCS) as a quantitative outcome measure, we demonstrated in a previous randomized trial that audio distraction, using relaxation music, could de-

Institution
[1] Department of Surgery, Prince of Wales Hospital, The Chinese University of Hong Kong, Hong Kong, China
[2] Department of Anesthesiology, Prince of Wales Hospital, The Chinese University of Hong Kong, Hong Kong, China

Corresponding Author
S. C. S. Chung, M.D. · Division of Upper Gastrointestinal Surgery · The Chinese University of Hong Kong · Prince of Wales Hospital · Shatin, NT · Hong Kong SAR · China · Fax: + 852-2637-7974 · E-mail: sydneychung@cuhk.edu.hk

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crease the dose of sedative medication required during colonoscopy [10]. In this study, we tested the hypotheses that visual distraction may also decrease the dose of sedative medication required during colonoscopy, and that audio and visual distraction may have additive beneficial effects when used in combination.

Patients and Methods

Between April and November 2001 we prospectively recruited 165 consecutive patients who were undergoing elective day-case colonoscopy into our trial (age range 16 – 75 years). We excluded patients who had had a colectomy and those with a history of allergy to propofol and/or alfentanil. A total of 12 eligible patients were not willing to participate in the study and were excluded before randomization: six did not want any sedation; four did not want to be randomly allocated to a study group; and two had hearing problems.

Participating patients were randomly assigned using computer-generated numbers into three groups to receive different modes of sedation: group 1 received visual distraction and patient-controlled sedation (PCS); group 2 received audiovisual distraction and PCS; and group 3 received PCS alone.

PCS was delivered by means of a Graseby 3300 PCA pump (Graseby Medical Ltd., Hertfordshire, UK), using a mixture of propofol (200 mg in 20 ml) and alfentanil (0.5 mg in 1 ml) in a 25-ml syringe. The drugs were delivered in response to pressure on a hand-held button controlled by the patient. Each bolus (0.5 ml) delivered 4.8 mg propofol and 12 µg alfentanil. No loading dose was used and the lock-out time of the PCA machine was set at zero. Despite the zero lock-out time, a few seconds were required for the pump to deliver the pre-set bolus. All patients were instructed in the use of the hand-held button before colonoscopy.

Audiovisual distraction or visual distraction was provided by an Eyetrek system (Olympus, Tokyo, Japan) with a pre-set home-made movie (mainly scenic views) with or without classical music (Figure **1**). Every patient randomly allocated to receive these modes of distraction therefore watched the same movie and listened to the same music. Group 1 patients wore the same Eyetrek system with earphones even though they had no music to listen to. As a result, the endoscopists did not know whether patients were in group 1 or group 2. Nasal oxygen (2 l/min) was given to all patients, and oxygen saturation and blood pressure were continuously monitored throughout the procedure (Figure **2**). All colonoscopies were performed by one of four surgical endoscopists, who had each done more than 300 similar procedures before. Colonoscopies in all three groups were distributed evenly between the four endoscopists.

The primary outcome measure was the dose of PCS consumed. Other outcome measures included the number of hypotensive episodes (systolic blood pressure < 90 mmHg); oxygen desaturation (SaO_2 < 90 %); recovery time (recovery was assessed every 5 minutes by an independent recovery nurse until the patient was orientated to time, place, and person, and was able to serially subtract 7 from 100); pain score (using a 10-cm unscaled visual analog scale on which 0 = no pain and 10 = very painful); satisfaction score (using a 10-cm unscaled visual analog scale on which 0 = not satisfied and 10 = very satisfied); and patients' willingness to use the same mode of sedation again if the procedure were to be repeated. All recovery nurses were blinded as to the sedation group to which patients had been assigned.

Figure **1** The Eyetrek system (Olympus, Tokyo, Japan).

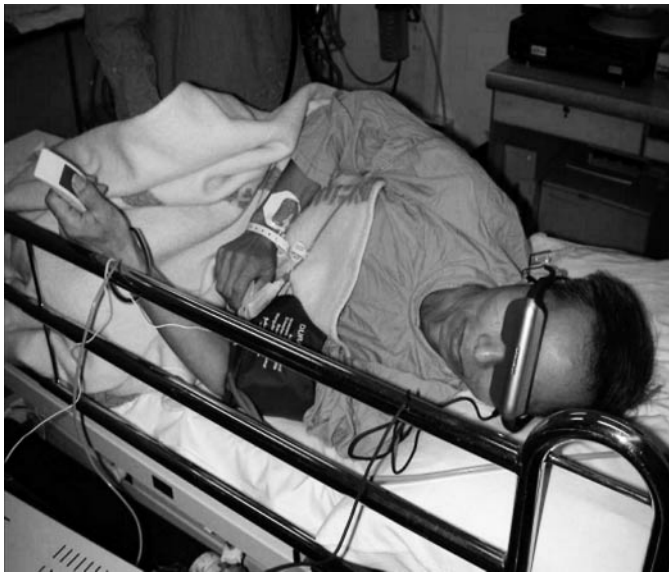

Figure **2** The endoscopy suite set-up for colonoscopy in a patient receiving audiovisual distraction and patient-controlled sedation.

The study protocol was approved by the hospital's ethics committee. All patients signed an informed consent before they were recruited for the study.

Statistical Analysis

We based our estimate of the sample size required for the study on the assumption that there would be a 30 % reduction in the dose of sedative medication required after visual distraction was provided. With a *P* value of 0.05 and a power of 80 %, we needed at least 48 patients in each group.

Table **1** Patient characteristics and indications for colonoscopy

	Group 1 Visual distraction + PCS (n = 52)	*Group 2 Audiovisual distraction + PCS (n = 52)*	*Group 3 PCS alone (n = 53)*	*P value*
Age, mean ± SD, years	45.6 ± 10.2	48.8 ± 11.3	46.3 ± 11.4	0.97
Gender, male:female	25:27	27:25	23:30	0.68
Indications for colonoscopy				0.13
– Rectal bleeding	16	22	23	
– Change of bowel habit	12	6	14	
– Constipation	2	3	5	
– Abdominal pain	4	8	4	
– Surveillance	11	5	6	
– Anemia	0	1	0	
– Others	7	7	1	
ASA grading				0.17
I	46	40	47	
II	6	12	5	
III	0	0	1	
Previous colonoscopy	19 (37 %)	15 (29 %)	12 (23 %)	0.29

PCS, patient-controlled sedation; ASA, American Society of Anesthesiology.

Table **2** Features of the colonoscopy procedures

	Group 1 Visual distraction + PCS (n = 52)	*Group 2 Audiovisual distraction + PCS (n = 52)*	*Group 3 PCS alone (n = 53)*	*P value*
Mean duration of procedure ± SD, minutes	16.7 ± 10.6	13.4 ± 6.9	16.6 ± 9.5	0.11
Complete colonoscopies, n (%)	49 (94 %)	48 (92 %)	49 (92 %)	0.91
Polypectomies, n (%)	8 (15 %)	9 (17 %)	9 (17 %)	0.96
Episodes of hypotension, n (%)	5 (10 %)	5 (10 %)	7 (13 %)	0.79
Median recovery time, minutes (IQR)	5 (0–5)	5 (0–5)	5 (0–5)	0.83

PCS, patient-controlled sedation; IQR, interquartile range.

The Pearson chi-squared test was used for categorical data analysis. For continuous data, a one-way analysis of variance (ANOVA) (for three groups) was used to test the hypothesis of equality of means. If there were concerns about deviations from normality, the nonparametric Kruskal-Wallis test was used to test the hypothesis of equality of medians. Parametric summary statistics are presented as mean ± SD. Nonparametric summary statistics are presented as medians (interquartile range, IQR). The Tukey test was used to detect which of the three groups were different following a rejection of the null hypothesis in a one-way ANOVA. Fisher's exact test was used to perform a post hoc analysis of categorical data. The Statistical Package for Social Sciences (SPSS) version 9.0 for Windows (SPSS Inc., Chicago, Illinois, USA) was used for statistical analysis. A *P* value of 0.05 or less was regarded as statistically significant.

Results

Eight patients were excluded after randomization: four patients had incomplete assessment forms and four patients did not receive proper PCS due to mechanical failure during the procedure. As a result, 157 patients were entered into the final analysis. The three groups were comparable with regard to age, sex, indications for colonoscopy, American Society of Anesthesiology (ASA) grading, history of previous colonoscopy, number of complete colonoscopies, hypotensive episodes, and recovery time (see Tables **1** and **2**).

Table **2** summarizes the features of the procedure itself in the three groups. No episodes of apnea or desaturation occurred during the procedures in any of the three groups. The mean duration of the procedure was shorter in group 2, but this was not statistically significant. One patient in group 2 and one patient in group 3 developed severe abdominal pain after the procedure. Both patients were admitted for overnight observation and no further treatment was required.

The results of the study are summarized in Table **3**. The mean dose ± SD of propofol used in group 2 (0.81 mg/kg ± 0.49) was significantly lower than the mean dose ± SD used in groups 1 and 3 ($P < 0.01$, one-way ANOVA). Post hoc analysis using the Tukey test showed that the differences between groups 1 and 2 and between groups 2 and 3 were significant (group 1 vs. group 2, $P = 0.01$; group 2 vs. group 3, $P < 0.01$; group 1 vs. group 3, $P = 0.10$). The doses of PCS used in each group did not vary ac-

Table **3** Summary of results

	Group 1 visual distraction + PCS (n = 52)	*Group 2 audiovisual distraction + PCS (n = 52)*	*Group 3 PCS alone (n = 53)*	*P value*
Mean dose of propofol ± SD, mg/kg	1.17 ± 0.81	0.81 ± 0.49	1.18 ± 0.60	< 0.01*
Mean pain score ± SD (range 0 – 10)	6.2 ± 2.2	5.1 ± 2.5	7.0 ± 2.4	< 0.01* †
Mean satisfaction score ± SD (range 0 – 10)	8.2 ± 2.4	8.4 ± 2.4	6.1 ± 2.9	< 0.01* †
Willing to repeat procedure with same mode of sedation, n (%)	38 (73 %)	44 (85 %)	28 (53 %)	< 0.01#

PCS, patient-controlled sedation; * One-way ANOVA; † Kruskal-Wallis test; # Pearson chi-squared test.

cording to which of the four endoscopists carried out the procedure.

Similarly, the mean pain score ± SD was significantly lower in group 2 (5.1 ± 2.5; $P < 0.01$, one-way ANOVA). Post hoc analysis showed a significant difference between groups 2 and 3 (group 1 vs. group 2, $P = 0.05$; group 2 vs. group 3, $P < 0.01$; group 1 vs. group 3, $P = 0.21$; Tukey test).

The mean satisfaction score + SD on was higher in group 2 (8.4 ± 2.4) than in groups 1 (8.2 ± 2.4) and 3 (6.1 ± 2.9) ($P < 0.01$; one-way ANOVA). Post hoc analysis showed that the differences between groups 1 and 3 and between groups 2 and 3 were significant (group 1 vs. group 2, $P = 0.94$; group 2 vs. group 3, $P < 0.01$; group 1 vs. group 3, $P < 0.01$; Tukey test).

The majority of patients in groups 1 and 2 were willing to repeat the procedure using the same mode of sedation (73 % in group 1 and 85 % in group 2; $P < 0.01$, chi-squared test). Post hoc analysis showed significant differences between groups 1 and 3 and between groups 2 and 3 (group 1 vs. group 2, $P = 0.23$; group 2 vs. group 3, $P < 0.01$; group 1 vs. group 3, $P = 0.04$; Fisher's exact test).

Discussion

The use of various distraction techniques to reduce pain and anxiety has been reported in other medical procedures [11 – 16]. The use of such techniques has not been well defined in gastrointestinal endoscopy. Lembo et al. reported that audio and visual stimulation could reduce patient discomfort during flexible sigmoidoscopy screening [17]. Others have reported that the use of music during endoscopy could alleviate anxiety and improve tolerance and compliance [18 – 20].

One of the difficulties when interpreting reports in the literature on this issue has been that these studies lacked objective outcome measures. The introduction of patient-controlled sedation (PCS) in colonoscopy [21] allowed us to measure quantitatively the amount of sedatives consumed by each patient, thus providing an objective outcome measure for clinical research on sedative requirements.

In our previous study, we demonstrated that audio distraction using relaxation music could decrease the dose of PCS required and improve patients' acceptance of colonoscopy [10]. In this study we tested the hypothesis that visual distraction might also decrease the dose of sedative medication required during colonoscopy. Our results suggest that visual distraction alone does not lead to a decrease in the dose of sedative medication patients require. However, when audio distraction was added there was a significant decrease in the dose of sedative medication consumed. Because our last study design was similar to the current one, we did not think it necessary to recruit a fourth group of patients (receiving audio distraction alone) into this trial.

Based on our results, we believe that audio distraction is the essential component that contributes to the decrease in the dose of sedative medication. The duration of colonoscopy was noted to be shorter in group 2 (although this did not reach statistical significance) despite the fact that the number of therapeutic procedures carried out during colonoscopy was the same as in the other groups. We believe that the shorter duration of colonoscopy in this group might be related to the fact that less pain is experienced, an effect of the audio distraction. It is conceivable that if patients experience less pain during the procedure, both the duration of the procedure and the consumption of sedative medication will be lower.

Exactly how audio distraction decreases the dose of sedation remains a subject of conjecture. Previous studies reported that relaxation music could alter physiological parameters such as heart rate and blood pressure, decrease pain perception, and alleviate anxiety [18,19,22]. In our study, although a lower pain score was observed in group 1 (visual distraction + PCS), compared to group 3 (PCS alone), the difference did not reach statistical significance on post hoc analysis. When audio distraction was added, in group 2 (audiovisual distraction + PCS) patients, there was a statistically significant decrease in pain score when compared with patients on PCS alone (group 3). It is possible that audio distraction played an important role in decreasing pain perception in this study.

On the other hand, both visual distraction and audiovisual distraction can improve patients' satisfaction scores. Although a higher satisfaction score was observed in group 2 (audiovisual distraction + PCS) compared with group 1 (visual distraction +

PCS), the difference did not reach statistical significance on post hoc analysis. In this regard, therefore, adding audio distraction did not provide additional benefit.

There were significantly more patients in groups 1 (visual distraction + PCS) and 2 (audiovisual distraction + PCS) who were willing to repeat the procedure using the same mode of sedation than there were in group 3 (PCS alone). On post hoc analysis, the difference between groups 1 and 2 was not significant. We believe that both visual and audiovisual distraction could improve the acceptability of the procedure to patients.

The current study has several limitations. First, our endoscopists were not blinded with regard to the use of audiovisual equipment during the procedure, which may possibly be an area of bias. Nonetheless, our primary outcome was the dose of sedative medication consumed, which was controlled by the patients and not by the endoscopists, so minimizing the bias. Secondly, patients in group 3 may have felt that they were receiving "inferior" treatment because they did not receive any "new" treatment and thus may have expressed lower levels of satisfaction. Thirdly, we only recruited day-case patients into the current trial and the mean age of our patients was therefore relatively low. Whether our findings can be reproduced in an older population or in inpatients will need to be determined by further studies. Lastly, our study was limited in that we used a home-made movie with scenery and classical music. Further research would be necessary to elucidate whether different types of movies and music have different effects.

In conclusion, this randomized trial demonstrated that visual distraction alone did not decrease the dose of sedative medication required by patients undergoing colonoscopy. When audio distraction was added, the dose of sedation and the pain score decreased significantly. The use of audio distraction as an adjunct to sedation can therefore potentially reduce the cost and dose-related complications associated with the use of sedative medication. Visual distraction alone or in combination with audio distraction can, however, improve patients' satisfaction with and tolerance of colonoscopy. Inasmuch as this is a noninvasive method, we recommend using distraction techniques, particularly audio distraction, to improve outcomes of elective day-case colonoscopy.

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