Evaluation of postural stability after low-dose droperidol in outpatients undergoing gynaecological dilatation and curettage procedure

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Background. Low-dose droperidol is suggested to be cost-effective in preventing nausea and vomiting after ambulatory surgery. This clinical study evaluated patient postural stability using a computerized force platform after an i.v. dose of droperidol 0.625 mg in outpatients undergoing gynaecological dilatation and curettage procedures.

Methods. After institutional approval and informed consent, 120 females were randomly assigned to receive either 0.9% saline (placebo) or droperidol 0.625 mg i.v. before surgery. Anaesthesia was induced with propofol 2–2.5 mg kg^{-1} and fentanyl 50–100 μg, and was maintained with intermittent boluses of propofol 25–50 mg and fentanyl 25–50 μg i.v. After operation, the Post-Anaesthesia Discharge Score (PADS), patient self-assessment scores for pain, nausea, drowsiness and dizziness, and extrapyramidal symptoms were recorded. Body sway velocity was measured while the patient was standing on a firm surface with eyes open then closed *vs* standing on a foam surface with eyes open then closed, at the time of arrival in the operation holding area (baseline), on achieving a PADS of 9 after surgery and on discharge home.

Results. At the time of achieving a PADS of 9, body sway was significantly greater in the droperidol group than in the placebo group (overall 61% *vs* 33% above baseline). There were no differences between groups with respect to scores for pain, nausea, drowsiness and dizziness. Three patients (5%) in the droperidol group reported nervousness and restlessness postoperatively (not significant).

Conclusion. Low-dose droperidol 0.625 mg i.v. for anti-emetic prophylaxis can cause balance disturbances in females after gynaecological dilatation and curettage procedures.

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Droperidol is a butyrophenone tranquilizer with potent neuroleptic and anti-emetic effects. A small intravenous (i.v.) dose of droperidol has been suggested to be the most cost-effective single drug therapy for prevention of postoperative nausea and vomiting (PONV) in outpatients at low to moderate risk of PONV.[1–3] Droperidol 0.625 mg has been reported to be effective in preventing PONV and to be associated with fewer adverse effects, such as sedation and dystonic reactions, when compared with droperidol 1.25 mg.[2–4] Although droperidol at such a small dose did not appear to delay the patient's early recovery after ambulatory surgery,[2 3] its potential to cause disturbances in the central nervous system (CNS) has not been evaluated fully.

Balance function is an important factor to be considered when assessing recovery and street fitness after ambulatory anaesthesia. We hypothesized that, after a small dose of droperidol, patients might have a degree of CNS suppression which could result in detectable balance disturbances. As postural stability, measured with a force platform, has been reported to be useful in the assessment of balance disturbances after general anaesthesia and sedation,[5–8] we designed this randomized, double-blind, placebo-controlled

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trial to evaluate postural stability using a computerized force platform, the Balance Master (model 6.1; NeuroCom® International, Clackamas, OR, USA), after a small dose of droperidol in outpatients undergoing gynaecological dilatation and curettage. The droperidol dose of 0.625 mg i.v. was chosen because this is the commonly accepted effective dose for anti-emetic prophylaxis in the ambulatory setting.

Methods

After we had obtained Institutional Ethics Board approval for the study, 120 consenting ASA I female outpatients, aged 18–50 yr, scheduled for dilatation and curettage were randomly assigned to the placebo or droperidol group on the basis of a computer-generated table of random numbers. Patients were excluded from the study if they had known musculoskeletal diseases, psychological disorders, symptoms suggestive of vestibular or neurological disorders, current or past medical diagnosis or injury affecting balance, or a history of alcohol or drug abuse.

Patients were given naproxen 500 mg orally approximately 60 min before the induction of anaesthesia for prophylactic analgesia. An i.v. line was established before the patient entered the operating room. Upon arrival in the operating room, the patient was given a study drug before induction of anaesthesia. The study drug was either 0.9% saline 1 ml or droperidol 0.625 mg in 0.9% saline 1 ml, and was prepared according to the patient's group assignment by a research assistant who was not involved in the study. The investigators, anaesthetists and study patients were blinded to the treatment group.

Anaesthesia was induced with propofol 2–2.5 mg kg^{-1} and fentanyl 50–100 μg i.v. and maintained with intermittent boluses of propofol 20–50 mg i.v. and fentanyl 25–50 μg i.v. if necessary. All patients breathed spontaneously and 100% oxygen was administered with a facemask. No other medications were used during anaesthesia. After completion of surgery, emergence times were determined at 1-min intervals until the patients were awake (i.e. opened their eyes on verbal command) and orientated (i.e. correctly stated the date, place and their name). Upon arrival in the postanaesthesia care unit (PACU), the Post-Anaesthesia Discharge Score (PADS)[9] was assessed at 15-min intervals until the patient was ready to go home. The PADS is based on five main criteria: vital signs, ambulation, pain, nausea/vomiting and surgical bleeding. Each of the criteria is graded from 0 to 2 and a summated score of 9–10 indicates that the patient is fit for discharge. In addition to PADS, postoperative pain, nausea, drowsiness and dizziness were evaluated using 10-point self-assessment verbal scores (0=none, 10=worst imaginable) at 30-min intervals until the time of discharge home. Rescue medication for pain or emesis was given when the self-assessment verbal score for pain or nausea was greater than 4 or the patient requested it. These medications included a paracetamol–codeine compound 1–2 tablets orally and metoclopramide 10 mg i.v., for pain and emesis respectively.

Postural stability was assessed using the Balance Master Static Sway test (Modified Clinical Test for Sensory Interaction on Balance)[10] on arrival in the operation holding area (pre-anaesthesia baseline), on achieving a PADS of 9 after completion of the procedure and on actual discharge home. The Balance Master system is a mobile piece of equipment (capable of bedside measurement) consisting of dual static forceplates and a computer monitor. Each footplate rests on two force transducers with the sensitive axes oriented vertically. The transducers in turn provide input to the computer. The software program filters the centre-of-pressure data and then calculates, tracks and displays the centre of gravity (COG) on the monitor. Data from the assessments were recorded in the form of COG sway or moving velocity (deg s^{-1}). The Modified Clinical Test for Sensory Interaction on Balance measures the sway velocity (deg s^{-1}) of COG under four conditions: (i) standing on a firm surface with eyes open; (ii) standing on a firm surface with eyes closed; (iii) standing on a foam surface with eyes open; (iv) standing on a foam surface with eyes closed. During the test, each condition was repeated three times (10 s each time) and the average value was recorded.

In addition to the assessments of postural stability and self-rated common postoperative side-effects, extrapyramidal symptoms were evaluated. All patients were requested to answer the following four questions at the times of discharge from the PACU and discharge home: (i) since waking up, have you felt restless or unable to sit still? (ii) have you experienced tremor or shaking? (iii) have you felt nervous or jumpy, and (iv) have you had any unusual physical sensation? The patient was requested to provide possible or suspected reasons for any symptoms. The same questions were asked again during a 24-h follow-up telephone call. Patients who were not reached 24 h after surgery were called again on the succeeding two days.

A power analysis was performed before initiating the study on the basis of the results of testing a population of clinically asymptomatic subjects who had a postural stability assessment on the Balance Master (NeuroCom International, Balance Master version 6.1 operator's manual, 1998). The mean (SD) of the COG sway velocity with the patient standing on a foam surface with eyes closed in subjects aged 20–69 yr is 1.49 (0.45). Using this estimate, the detection of a 20% clinically relevant difference in this primary end-point between the two treatment groups would require 49 subjects per group (α=0.05, β=0.1) (statistical software, nQuery Advisor™ 1.0, USA).

Unpaired (two-sample) and paired (one-sample) *t*-tests were performed for comparisons of all continuous variables between and within the study groups, the Kruskal–Wallis test was performed for comparisons of patient self-assessment verbal scores, and the χ^2 test with Yates' continuity correction, as appropriate, was performed for comparisons

Table 1 Patient characteristics, duration of surgery and anaesthesia, anesthetic and analgesic doses, and fluid volumes in the two study groups. Data are mean (SD or range)

	Placebo	Droperidol
Number of patients	58	60
Age (yr)	29 (18–50)	30 (18–50)
Weight (kg)	62 (14)	61 (12)
Height (cm)	160 (6)	159 (6)
Anaesthesia time (min)	8.3 (3.2)	8.3 (2.2)
Surgery time (min)	5.7 (2.4)	5.3 (1.5)
Propofol (mg)	198 (41)	199 (50)
Fentanyl (μg)	55 (17)	55 (14)
Total i.v. fluid (ml)	477 (177)	468 (195)

Table 2 COG sway velocities (deg s^{-1}) in the two study groups. Data are mean (SD). COG=centre of gravity; PADS=Post-Anaesthesia Discharge Score. *P<0.01 *vs* pre-anaesthesia value; †P<0.01 *vs* placebo group

	Placebo	Droperidol
Firm surface, eyes open		
Pre-anaesthesia	0.28 (0.08)	0.29 (0.08)
PADS 9	0.38 (0.13)*	0.47 (0.17)*†
Discharge home	0.30 (0.11)	0.32 (0.10)
Firm surface, eyes closed		
Pre-anaesthesia	0.35 (0.11)	0.32 (0.11)
PADS 9	0.46 (0.20)*	0.55 (0.24)*†
Discharge home	0.37 (0.14)	0.36 (0.12)
Foam surface, eyes open		
Pre-anaesthesia	0.54 (0.14)	0.57 (0.15)
PADS 9	0.63 (0.21)*	0.85 (0.42)*†
Discharge home	0.54 (0.19)	0.56 (0.11)
Foam surface, eyes closed		
Pre-anaesthesia	1.26 (0.42)	1.29 (0.34)
PADS 9	1.57 (0.51)*	1.93 (0.52)*†
Discharge home	1.28 (0.27)	1.35 (0.36)

of other non-parametric variables. Data are expressed as mean (SD), and P values of less than 0.05 were considered statistically significant.

Results

One hundred and twenty patients were recruited for the study. Two patients in the placebo group withdrew from the study because they were unwilling to perform the balance test postoperatively.

The droperidol and placebo groups were comparable with respect to age, weight, height, duration of surgery and anaesthesia, intraoperative propofol and fentanyl doses and total fluid volumes (Table 1). There were no differences between the groups with respect to the pre-anaesthesia baseline values of the Balance Master scores (Table 2) and verbal scores for pain, nausea, drowsiness and dizziness (Table 3). The incidence of postoperative nausea was 5% in the control and droperidol groups. Eleven patients (18%) in the droperidol group and 18 patients (31%) in the control group received rescue pain medication (P<0.05) and no patients in either group received rescue anti-emetic.

Table 3 Recovery times and postoperative 10-point self-assessment scores in the two study groups. Data are expressed as mean value (SD) or median (range). PADS=Post-Anaesthesia Discharge Score

	Placebo	Droperidol
Awakening time (min)	2.6 (1.7)	3.2 (1.8)
Orientation time (min)	4.8 (2.6)	5.8 (2.3)
Time to PADS 9 (min)	37 (10)	36 (6)
Discharge home (min)	92 (27)	102 (28)
Self-assessment score at PADS 9		
Pain	1.5 (0–6)	0 (0–6)
Nausea	0 (0–2)	0 (0–2)
Drowsiness	2 (0–4)	2 (0–6)
Dizziness	0 (0–4)	0 (0–5)

After surgery, times to awakening and orientation were similar in the droperidol and placebo groups (Table 3). At the time of achieving a PADS of 9 (approximately 36 min after the procedure), COG sway velocities were significantly increased above their pre-anaesthesia baselines in all the four testing conditions in both study groups, and these increases were significantly greater in the droperidol group (overall 61%) than in the placebo group (overall 33%) (Table 2). However, these differences were not noted at the time of patient discharge. There were no statistical differences between the two study groups in the times to achieve a PADS of 9 and discharge home (Table 3).

Three patients (5%) in the droperidol group reported 'unexplained restlessness' during recovery. Two of them reported that they were unable to sit still and felt nervous in the ambulatory surgical unit and one reported that she had a tremor and was anxious at the time of discharge home. The symptoms lasted for 2–3 h in all three patients and no one could give a possible suspected reason. None of the patients in the placebo group reported this problem. However, the incidence of restlessness in the droperidol group did not reach statistical significance. All patients were successfully followed up for the four questions about dysphoric reactions after discharge. Eighty-nine (75%) patients were reached in the 24-h telephone calls and 29 (25%) patients were reached in the 48- or 72-h calls.

Discussion

Static posturography, measured with an instrumented force platform, has been used in clinical practice for assessing and differentiating disturbance of vestibular, visual and proprioceptive functions and central coordination.[7 11 12] It has been applied in aerospace medicine, otolaryngology, the evaluation of interactions of drugs with alcohol, studies of the susceptibility of humans to fall and measurements of recovery from anaesthesia. The reliability of outcome measures obtained using the Balance Master has been evaluated in healthy subjects.[13] Interclass correlation coefficients revealed excellent reliability of limits of stability measures and the position of the centre of gravity. Reliability and validity of measures obtained from 20 stroke

patients using the Balance Master suggest that the test–retest reliability of data is great for complex tests of balance.[14]

Droperidol 0.625 mg i.v. is one of the most recommended methods for the prevention of PONV.[1–3] In the ambulatory setting, it is important to know if this dose of droperidol has any potential for CNS suppression which may affect recovery in terms of ambulation. Although clinical observations in many previous studies have failed to find any adverse effects of droperidol at this dose, an objective instrumental measure, such as computed posturography, may reveal some evidence that balance function is affected in a way that may compromise recovery after ambulatory surgery.

In this study, we chose young females undergoing a minor gynaecological surgical procedure (i.e. dilatation and curettage) with an expected low incidence of PONV in an attempt to minimize the potential disturbance of balance caused by postoperative pain and emesis. In addition, the criticism of using a placebo in the study control group is avoided because the use of low-dose droperidol for antiemetic prophylaxis in this population is optional in our institution. Analgesic prophylaxis with naproxen may also have contributed to the minimal postoperative pain and emesis in this study. Because of the low incidence of PONV, the beneficial effects of droperidol on PONV could not be demonstrated.

All patients showed significantly increased body sway approximately 40 min after the bolus doses of i.v. propofol and fentanyl at the time when they had just regained the ability to walk independently. This may be explained by the residual adverse effects of i.v. propofol and fentanyl during the early recovery period. Previous posturographic studies[5 15] have demonstrated that patients who received propofol anaesthesia require 2 h or more to regain their balancing ability completely. Although no differences were found between the two study groups with respect to postoperative side-effects, patients who received small doses of droperidol had significantly more body sway than patients who received placebo in all static sway testing conditions. This indicates that the use of droperidol 0.625 mg i.v. was associated with an additional balance-compromising effect during the first postoperative balance testing time, i.e. approximately 40 min after completion of the procedure.

The balance-compromising effect associated with the use of a small dose of droperidol may be caused by droperidol's depressing effect on the CNS and enhancement of the residual effects of general anaesthetics and analgesics. Our results showed that the increase in body sway in the droperidol group compared with the placebo group occurred in all testing conditions, demonstrating a parallel compromising effect on the patient's somatosensory, visual and vestibular control of balance. However, all patients in both groups resumed their postural stability at the time of home discharge. In this study, the postural instability associated with droperidol 0.625 mg did not delay the time of discharge home significantly. However, we did not evaluate the effects of droperidol at higher doses on balance function.

Another adverse effect associated with the use of droperidol is extrapyramidal symptoms. This side-effect was not reported with a dose of 0.625–1.25 mg.[2 3 16] However, some studies have shown an unexpected high incidence after a small dose of droperidol. Foster and colleagues[17] reported incidences of postoperative akathisia of 23 and 38% after droperidol doses of 0.5 and 1 mg respectively in females undergoing minor day-case surgery. Lim and colleagues[18] reported incidences of dysphoric reactions of 29.2 and 29% after droperidol doses of 10 and 20 $\mu g\ kg^{-1}$ respectively in women undergoing outpatient laparoscopy. In our study, three of sixty (5%) patients receiving droperidol 0.625 mg developed postoperative restlessness and anxiety. However, this was not statistically significant. The symptoms lasted for several hours after surgery but no acute dystonia or parkinsonism was noted. In conclusion, low dose droperidol 0.625 mg i.v. for antiemetic prophylaxis can cause balance disturbances after surgery.

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