Driving performance of outpatients achieving discharge criteria after deep sedation is worse than these of their escort-driver: a prospective observational study on simulator

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Abstract

Background: **Achieving post-anesthesia discharge criteria after surgery or outpatient procedures does not mean that the patient has regained all his or her faculties, such as driving. Although mandated by many clinical guidelines, there is no evidence that escort-drivers reduce the risk of traffic accidents after deep sedation. The purpose of this study was to evaluate that hypothesis that driving performance as measured using a driving simulation would not differ between patients who had undergone deep sedation for gastrointestinal endoscopy meeting discharge criteria and their escorts.**

Methods: **This prospective study included patients scheduled for ambulatory gastrointestinal endoscopy under deep propofol sedation (patient group) and their escorts (escort group). Driving performance of escorts and patients (when discharge criteria were met) was assessed using a driving simulator.**

Results: **30 patients and their escorts were included. Patients crossed the midline significantly more frequently than escorts (3 [2-4] (median [IQR]) and 2 [1-3] crossings, respectively, p=0.015]. Patients were speeding for a higher proportion of the distance traveled compared with escorts (37 (20)% (mean (SD)) and 24 (17)% in patients and escorts, respectively, p = 0.029). There were no significant differences between groups in other simulation parameters.**

Conclusions: **The ability to stay within the traffic lanes, as measured by the number of midline crossing during a simulated driving performance, is impaired in patients who meet discharge criteria after gastrointestinal endoscopy under deep sedation compared with their escorts. This finding does not support a practice of allowing patients to drive themselves home after these procedures.** (Acta gastroenterol. belg., **2023,** 86, **11-16**).

Keywords: Driving performance, deep sedation, GI endoscopy.

Introduction

The Post Anesthesia Discharge Scoring System (PADSS) developed by Chung et al. (1) defines discharge criteria after surgery or ambulatory procedures. Modified criteria (2) for scoring include vital signs, ability to ambulate, pain, postoperative nausea and vomiting, and surgical bleeding. Although widely utilized and clinically useful, achieving a modified PADSS score compatible with home discharge does not imply that the patient has regained full functioning, including the ability to drive.

Driving performance can be affected by many factors, including age, fatigue and drowsiness, depression, alcohol consumption, use of benzodiazepines, antidepressants, or opioids (3-6). Driving ability can also be impaired after general anaesthesia (7). Indeed, drugs used during general anaesthesia or deep sedation have the potential to reduce alertness through impaired attention, drowsiness or decreased responsiveness.

For this reason, some scientific societies recommend against driving 12 to 24 hours after sedation or general anaesthesia (8). This recommendation is based on studies showing that driving ability is impaired for up to 6 hours after general anaesthesia (7,9) in healthy young outpatients. However, another study has produced conflicting results in volunteers (10). In addition, there are no data in older outpatients with comorbidities, which now constitute a substantial proportion of the ambulatory surgical population. There is also little direct evidence that the practice of escort-driver as recommended by scientific societies can improve safety (11). Some authors have even shown that there was no accident when patients who had a low dose only-propofol sedation returned home unaccompanied one hour after the examination (12). Moreover, escorts are not always available, and the social pressure is significant to allow the patient to drive home alone after procedures such as endoscopy under deep sedation. Indeed, some escorts must take time off work, use vacation days, hire babysitters, and rearrange family and work schedules at the cost of financial, emotional, or professional hardship (13), which can result in delays or cancellations, same-day patient absences, and sometimes require a longer hospital stay.

Based on the study of Riphaus et al. showing that in patients sedated with propofol alone for endoscopic procedures, performance in the driving simulator 2 hours after sedation is similar to that before the endoscopic procedure (14) and in order to address the utility of an escort after deep sedation for gastrointestinal (GI) endoscopy, we hypothesised that the driving performance of patients who met the discharge criteria and their escorts

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did not differ. The purpose of our study was to measure and compare the driving performances, i.e., the ability to control one's vehicle under all circumstances, of patients with a modified PADDS score of 9 or greater to those of their escorts on a driving simulator.

Material and methods

1. Study design

This prospective observational study included patients scheduled for ambulatory GI endoscopy under deep sedation between end of March and May 2019 and their escort-drivers.

This study was approved by Comité d'Ethique Hospitalo-facultaire de Liège, Liège, Belgium (N° B7007201938885, President: Prof. Vincent Seutin) on March 22, 2019. A written informed consent was obtained from each participant.

2. Participant selection

Recruitment of patients and their escorts was performed on the day of the endoscopy. All adult patients admitted for an ambulatory GI endoscopy procedure (gastroscopy, colonoscopy, or combined examination) under deep sedation and their escorts were eligible.

Exclusion criteria were unavailability of the escort-driver for the duration of the examination, absence of a driver's license, and absence of driving for 5 years.

3. Anaesthesia and recovery

Upon arrival in the procedure room, a catheter was inserted in a peripheral vein, and standard monitoring including a 5-lead ECG, NIBP, oximeter, and capnometer was applied. All patients received supplemental oxygen during the procedure to keep peripheral oxygen saturation >94%. Sedation was induced and maintained with a propofol infusion. Sufentanil, midazolam, dehydrobenzperidol, or lidocaine, were also used based on the patient's history or the pre procedure clinical condition. At the end of the endoscopy, the patient was transferred to the post anaesthesia care unit. Patients were monitored in the post anaesthesia recovery unit until their Aldrete score (15) reached at least 12, at which time they were transferred to the outpatient unit. Patients were eligible for discharge when they achieved a modified PADSS (see appendix 1) of 9 (2).

4. Driving skills evaluation

The driving test was performed when the patient achieved a modified PADSS of 9 and could leave the unit to go home with their escort, which is consistent with our practice, where it is not possible to keep patients beyond this time to ensure unit rotation. The driving skills of the escorts were assessed while the patient was undergoing the procedure. Assessment was performed using the driving simulator STISIM Drive® manufactured by Systems Technology, Inc. (California, USA) (Fig. 1). This simulator consists of 3 curved screens, a seat, a steering wheel with force feedback, a 5-speed gearbox, and a conventional car pedalboard with manual transmission. All driving assessments were performed by the same investigator.

Figure 1. — Driving simulator (STISIM Drive®) installed in the outpatient unit's facilities.

Prior to the performance assessment, the 9-point Karolinska Sleepiness Scale (KSS) (16), the Beck Depression Inventory-II (BDI-II) (17), and the STOP-BANG (18) were administered. Then each participant was trained to use the driving simulator for approximately ten minutes, allowing them to drive approximately 7 kilometres. The study assessment was performed immediately after this familiarization phase.

The study assessment consisted of a 35-kilometer journey including various driving zones reproducing the vicinity of the hospital: a wooded area for 3.6 km, an urban area for 8.3 km and a highway area for 23.2 km. The simulation was halted at the end of the journey or when the participant felt nausea that made carrying the driving test impossible.

5. Data collected

Participant characteristics included age, sex, year of license, driving habits (type of vehicle transmission, kilometres driven annually, type of route most travelled), and number of traffic accidents in the past 5 years. In addition, STOP-BANG scores, BDI-II scores, KSS scores, chronic medications used, including the use of benzodiazepines, antidepressants, and opioids, as well as weekly alcohol consumption were also collected for all participants. For patients, procedural data include type of endoscopy, duration of sedation, time elapsed from end of sedation to achieving an Aldrete score of 12, time elapsed between end of sedation to achieving a modified PADSS = 9 and, drugs used for sedation including their doses.

Data collected by the simulator during the driving assessment include travel time, number of collisions with other vehicles, number of collisions with a pedestrian, number of times over speed limit indicated on road signs, number of traffic light violations, number of speeding

violations, number of lane deviations (median line and shoulder), duration of speeding or travelling out of traffic line, and travelled distance while speeding or when out of traffic line.

The number of participants with nausea during the simulation as well as the number of simulations interrupted before the end because of nausea were also noted.

6. Sample size calculation

A power calculation based on previously published studies (19,20) found that a sample size of a total of 57 subjects (sum of patients and escorts) is required to demonstrate a difference of 3 midline traffic crossings, which we considered to represent a meaningful increase in the risk of accidents, with a power of 0.8 and an alpha of 0.05. Participants were recruited until complete data from 30 patients and 30 matched escorts were obtained.

7. Statistical analysis

Statistical analysis was performed using JMP version 14.2.0 software (SAS Institute Inc.).

For analysis, participants were divided into 2 groups: the patient group and the escort group.

Normal distribution of the data was checked using the Shapiro-Wilk test. Results are expressed as mean ± SD or median [IQR, 25 to 75] according to their normal distribution or not or as number (%). Statistical comparisons were performed using Student t-test, Mann-Whitney test, or chi-square test. The primary outcome of this analysis was the number of midline traffic crossings. Other parameters of the driving simulation were analysed as secondary outcomes.

In order to identify predictors of the number of midline traffic crossings in the patient group, an adjustment (simple regression or ANOVA) was performed between the number of midline traffic crossings as response variable and each of the participant characteristics and procedural data as factors. A multivariate regression model (standard least squares) for the response variable was then used by including in the model quantitative factors with a p-value < 0.1 in the adjustment. For these analysis, outliers for propofol dose or sedation duration were removed using the boxplot.

A *P* value of less than 0.05 was considered significant.

3. Results

During the study period, 119 patients met the inclusion criteria of undergoing gastrointestinal endoscopy under deep sedation with a stay in the ambulatory unit when the investigator conducting driver simulator testing was available. Of these, 79 patients were asked to participate in the study. Forty-three patients declined to participate because of lack of escort time after the test and one patient did not have a driver's license. Three patients declined to participate after sedation because of fatigue. Thirty-two patients participated to the driving simulation. Data from 2 patients were lost and could not be analysed, such that the data from 60 participants (30 patients and 30 escorts) were included in the analysis.

1. Participant characteristics

The characteristics of the participants by group are presented in Table 1. Escorts had more years of driving experience compared with patients and were less likely to report frequent highway driving.

Table 1. — **Participant characteristics**

	Patient group n=30	Escort group n=30	P-value
Demographic data			
Sex Ratio Male/Female	14(47) / 16(53)	18(60) / 12(40)	0.29
Age, years	55.3 ± 12.2	57.8 ± 9.8	0.40
Driving data			
Number of years since obtaining driver's license	32.1 ± 12.8	39.8 ± 10.7	0.013
Usual vehicle type, automatic / manual transmission	3(10) / 27(90)	6(20) / 24(80)	0.27
Participants traveling as a driver < 15,000 km / year	11(37)	14 (47)	0.43
Most frequently used route types, Highway / Mixed / City / Rural	8(27) / 17(57) / 5(16) / 0(0)	3(10) / 12(40) / 4(13) / 11(37)	0.003
Number of accidents in the last 5 years	0 (0 – 0)	0 (0 – 0)	0.72
Clinical data			
Participants with a STOP-BANG = or > 3/8	14 (47)	18 (60)	0.30
Participants regularly using benzodiazepines	3 (10)	3 (10)	1.00
Participants regularly using antidepressants	6 (20)	8 (27)	0.54
Participants regularly using morphine or derivatives	0 (0)	0 (0)	1.00
Weekly alcohol consumption, units	1 [0 to 6]	2 [0.5 to 7]	0.26
Total BDI-II score (max. 9)	4 [1 to 8.25]	4.5 [1 to 9.25]	0.83

Data are expressed as number (%); mean ± SD or median [IQR 25-75].

Table 2. — **Procedure data**

	Patient group n=30
Type of procedure: Colonoscopy Gastroscopy Gastro and colonoscopy combined	 25 (83) 1 (3) 4 (14)
Duration of sedation, minutes	25 [19-5.5]
Time from end of sedation to Aldrete score = 12, minutes	45 ± 17
Time from end of sedation to modified PADSS=9, minutes	77 ± 20
Time from Aldrete score = 12 to PADDS = 9, minutes	30.5 [19 to 45]
Propofol dose, in milligrams	298 ± 133
Patients receiving sufentanil	9 (30)
Sufentanil dose, micrograms	5 ± 1.25
Patients receiving midazolam	9 (30)
Midazolam dose, milligrams	1.6 ± 0.5
Patients receiving dehydrobenzperidol (DHBP)	3 (10)
DHBP dose, milligrams	1.25 ± 0
Patients receiving lidocaine	26 (87)
Lidocaine dose, milligrams	65 ± 19

Data are expressed as number (%), mean ± SD or median [IQR 25-75]

2. Anaesthetic procedure data

The details of the anaesthetic procedure are listed in Table 2. Most patients received colonoscopy, with a median duration (IQR, 25-75) of sedation of 25 [19 to 35.5] minutes and a mean ± SD total propofol dose of 298 ± 133 milligrams. A minority of patients received adjuvant drugs, and almost all met discharge criteria (i.e., modified PADDS of 9) less than 2 hours after the start of sedation.

3. Simulation data

The time from achieving discharge criteria to the start of driving simulation was 35 [30 to 45] minutes. KSS scores before simulation were not significantly different in patients and escorts (4 [3 to 5] and 3 [2.75 to 4.25] in patients and escorts, respectively (P=0.12). After the simulation, KSS scores were significantly higher in the patients compared with escorts (5 [3 to 6] and 3 [2 to 5.5] in patients and escorts, respectively, P=0.014). Seven patients and five escorts experienced nausea during the driving simulation, which was halted 4 times in patients and 3 times in escorts.

For the primary outcome of interest, patients crossed the midline significantly more frequently than escorts (3 [2 to 4] and 2 [1 to 3] crossings, respectively, P=0.015] (Table 3). Patients were speeding for a higher proportion of the distance travelled compared with escorts (37 ± 20 and 24 ± 17 in patients and escorts, respectively, P= 0.029). There were no significant differences between groups in other simulation parameters.

4. Predictors of the number of midline traffic crossing in patients

The adjustment for the number of midline traffic crossing in the patient group showed a significant relationship between the latter and the time from end of sedation to modified PADSS=9 (r=0,52; P=0.006) and the sufentanil dose (r=0.41; P=0.03). A p-value < 0.10 was also observed for a positive STOP-BANG (P=0.06) and the weekly alcohol consumption (r=-0.33; P=0.09). Multivariate analysis did not reveal any predictor.

Table 3. — **Simulation data**

	Patient group n=30	Escort group n=30	p-value
Travel time (min)	29.2 [25.5 to 30.7]	28.7 [27.2 to 31.5]	0.65
Collisions with another vehicle (n)	0 [0 to 0.25]	0 [0 to 0.25]	0.74
Collisions with a pedestrian (n)	0 [0 to 0]	0 [0 to 0]	0.95
Number of speeding violations (n)	25 ± 9	23 ± 12	0.39
Proportion of time over speed limit (%)	28 [19 to 38]	23 [11.7 to 35.6]	0.12
Proportion of distance over speed limit (%)	37 ± 20	24 ± 17	0.029
Speeding tickets (n)	0 [0 to 0]	0 [0 to 0]	1.00
Number of midline crossings (n)	3 [2 to 4]	2 [1 to 3]	0.015
Number of shoulder passes (n)	22 ± 12	19 ± 13	0.34
Proportion of time out of traffic lane (%)	4.19 [2.86 to 5.72]	3.575 [1.47 to 4.96]	0.19
Proportion of distance out of traffic lane (%)	3.28 [2.35 to 4.77]	3.005 [1.07 to 4.1225]	0.25
Broken stops (n)	0 [0 to 0]	0 [0 to 0]	1.00
Stops at traffic lights (n)	3 [3 to 3]	3 [3 to 3]	0.75
Traffic light ticket (n)	0 [0 to 0]	0 [0 to 0]	0.56

Data are expressed as mean ± SD or median [IQR 25-75).

Discussion

The main finding of this study is that the ability to stay within the traffic lanes, as measured by the number of midline crossing during a simulated driving performance, is impaired in patients who meet discharge criteria after gastrointestinal endoscopy under deep sedation compared with their escorts.

Allowing patients to drive home after propofol sedation remains controversial (21,22). Yet this practice can increase the flow of patients within the ambulatory endoscopy unit, potentially increase the number of patients willing to be scheduled, and avoid inconvenience for the escort driver, the pressure remains significant to allow the patient to drive home.

Because, fortunately, automobile accidents after ambulatory surgery remain rare events, work in this area has con-centrated on studying the effects of sedation on various parameters related to driving ability. Two prior studies focussed specifically on driving ability after outpatient procedures requiring general anaesthesia. Sinclair et al. assessed driving skills using a simulator in 12 healthy volunteers following 30 minutes of general anaesthesia with propofol, fentanyl, nitrous oxide, and desflurane, and on a separate control session without drug exposure. They found no significant difference in postanaesthetic driving skills at two, three, and four hours postanaesthetic, and the corresponding control sessions. Chung et al. assessed simulated driving skills in relatively healthy patients undergoing knee arthroscopy using propofol, fentanyl, midazolam, nitrous oxide, and desflurane or sevoflurane, and a matched group of health volunteers not receiving anaesthesia. Patients were assessed preoperatively and at 2 and 24 h postoperatively. Driving skills and alertness were significantly impaired 2 h postoperatively, but not a 24 h postoperatively. Several factors may explain the different results between these two studies, potentially including the duration of anaesthesia and effects of postoperative analgesics (which was not reported in the latter study). Our study aimed to contribute to this relatively limited literature by focussing on a specific common procedure requiring sedation, and by making a comparison of perhaps the most direct clinical relevance – the actual escorts who are driving these patients home after their procedures.

To further enhance clinical relevance, patients were tested in the driving simulator when they had achieved a PADSS of 9 which is the threshold generally used to allow hospital discharge of ambulatory patients. The time required to achieve this score of 9 was approximately equivalent to one elimination half-life of propofol (23) and similar to the interval used by Sinclair et al. (10).

As previously demonstrated, driving performance could be impaired by several factors. For example, sleep deprivation which may occur in the pre-procedure period could impair the circadian cycle and reduce alertness (24). Although, our pre-procedure KSS scores were not different in patients and escorts, the higher post simulation KSS score in our patients could have contributed to impaired skills, as it is known that impaired daytime alertness leads to increased lateral deviations during simulator driving (25), a phenomenon that we observed in patients compared with driver escorts. A prior study found that driving ability was impaired after 4 mg midazolam used for endoscopy sedation at 2 h post-procedure, but not at 60 min post-procedure after low-dose (40 to 80 mg) propofol (26). However, if nine subjects in the current study received midazolam, but at a low dose (mean 1.6 mg), we did not find a contribution of midazolam to impaired performance in our patients. Under our circumstances, age, process as a continuous variable, was not found to be a predictor of the number of midline traffic crossing. Also, we also adjusted the number of midline traffic crossing by age category with a threshold of 60 years, the age considered by the WHO as the beginning of old age. In this condition, we also did not observed differences between patients and escorts. But, considering a cut-off of 65 years, official retirement age in our country, a trend of more frequent midline traffic crossing was observed among patients over 65 years compared to the escorts. This shows that a single indicator, such as a modified PADSS of 9, is probably not sufficient to give the go-ahead for driving home and the definition of a cut-off age could be an interesting direction of research.

This study had several limitations. First, we chose the escorts as a control and not the patients themselves. Indeed, it is the practice of the escort that we wanted to question. Moreover, choosing the patient as a control raises the question of the timing of the initial measurement. We believe that a fasting patient, having undergone a colonic preparation with possible sleep restriction, sometimes anxious, is not in a normal state. In our circumstances, it was impossible to ask patients a baseline pre-test several days in advance. Second, three subjects declined the driving simulation postoperatively because of sleepiness, which would bias against finding impairment – yet impairment was found. Third, simulator performance may differ from that in real traffic. Consistent with prior studies, we utilized crossing the midline more often as an intermediate outcome for the risk of accidents.(19) Our sample size was insufficient to examine accidents themselves as outcomes; our results suggest that such a study design may not be ethical based on the results for our primary outcome of lane changes. Finally, the escorts had more driving experience and less highway experience, which can be a coping mechanism for the possible age-related decline in driving performance. (3) However, while these factors might have worked against the control group in terms of driving performance, we observed better performance in this group, which further strengthen our conclusions.

Conclusions

Some parameters of driving performance assessed by simulation of outpatients achieving discharge criteria

with a PADDS of 9 after deep sedation for gastrointestinal endoscopy are diminished compared to that of their escorts. This finding does not support a practice of allowing patients to drive themselves home after these procedures.

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Disclosure of interest

The authors report no conflict of interest.

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Appendix 1: Modified PADSS(2)

1. Vital signs
   2 = Within 20% of preoperative value
   1 = 20-40% of preoperative value
   0 = 40% of preoperative value
2. Ambulation
   2 = Steady gait / no dizziness
   1 = with assistance
   0 = None / dizziness
3. Nausea / vomiting
   2 = Minimal
   1= Moderate
   0 = Severe
4. Pain
   2 = Minimal
   1= Moderate
   0 = Severe
5. Surgical bleeding
   2 = Minimal
   1= Moderate
   0 = Severe

The total score is 10. With patients scoring > or = 9 considered fit for discharge home.