Significance of patient-controlled sedation during colonoscopy

Results from a prospective randomized controlled study

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SUMMARY

Background — In France, general anesthesia is given to more than 90% of patients undergoing colonoscopy although in several countries sedation is limited to intolerant patients. This study was carried out to determine whether Patient-Controlled Sedation (PCS) could provide a lighter sedation than general anesthesia adapted to the patient’s individual requirement.

Methods — Patients aged from 18 to 80 scheduled for elective colonoscopy were prospectively randomized to receive either standard sedation (control group) or patient-controlled-sedation (PCS). In the control group, patients received a continuous infusion of propofol. Patients in the PCS group were connected to an infusion pump containing propofol and self-administered 20-mg boluses as often as they required. An anesthetist was present throughout the procedure. Patient satisfaction measured on a visual analog scale four hours after colonoscopy was the main outcome criterion.

Results — From December 2002 to September 2003, 402 patients underwent elective colonoscopy, 173 of them were eligible and were asked to participate in the study. Seventy-two gave their informed consent and were prospectively randomized. The patients’ mean satisfaction scores were not statistically different between the two groups: 84.7 mm (PCS group) vs 91.5 mm (control group); P = 0.24. Mean doses of propofol (60 mg vs 248 mg; P < 0.001), depth of sedation and time before discharge (1.75 hours vs 4.45 hours) were significantly lower for patients in the PCS group; nine of them (25.7%) did not use the pump and had total colonoscopy without sedation. There were no statistically significant differences between the two groups regarding total duration of colonoscopy (19.4 min (PCS) vs 18 min (control)) difficulty and therapeutic procedures (biopsy or polypectomy). Two weeks after the procedure, 96.5% of patients in the PCS group were willing to repeat the examination under the same conditions vs 72.5% of patients in the control group (P = 0.03).

Conclusions — Our results demonstrate that need of sedation is widely overestimated in France. A subset of our patients is willing to consider colonoscopy without general anesthesia. For them, PCS with propofol is an effective and very well accepted form of sedation.

Introduction

Can use of anesthesia for colonoscopic procedures be reduced? The question has been raised for many years but remains a controversial issue concerning who should perform the anesthesia, the appropriate patient population, and the type of sedation [1-4].

In France, more than 90% of colonoscopic procedures are conducted under general anesthesia, which can be performed only by a anesthetist [5]. This “all-or-none” attitude is however challenged by certain facts. First, general anesthesia hinders access to colonoscopy and increases its cost. In addition, this attitude is an exception compared with practices in other countries [6-10]. In Finland [6, 7] and Japan [9], colonoscopy is generally performed without sedation. In the United States, Switzerland
and Australia, endoscopists can administer anesthetic agents themselves and often use light sedation.

We aimed to know whether anesthetic practices for colonoscopy could be changed in France and whether the number of procedures performed under general anesthesia could be reduced. This led us to conduct a prospective study comparing standard anesthesia administered by an anesthetist and Patient Controlled Sedation (PCS). PCS is a technique derived from self-administered sedation protocols used for the treatment of postoperative and obstetrical pain. PCS has been used for colonoscopy for many years in other countries and has provided good results in terms of patient satisfaction and safety [11-15]. The principle of sedation-as-needed might offer an attractive solution to this controversial issue in France.

Methods

This was an open controlled randomized prospective study. The main objective was to demonstrate that Patient-Controlled-Sedation (PCS) is a satisfactory alternative for certain patients. Patient satisfaction with anesthesia, measured on a visual analog scale (0 mm = very dissatisfied, 100 mm = very satisfied), was the main outcome criterion.

Subjets

Patients aged 18-80 years with an indication for colonoscopy were eligible for inclusion. Criteria for non-inclusion were: ASA class IV, contraindication for propofol, pregnancy, concomitant indication for an upper endoscopic procedure, strong suspicion of colonic cancer (obstruction, liver metastasis), emergency procedure, therapeutic procedure and/or indication for coloration, severe psychiatric disease, inability to use the pump, inability to read French, inability to sign consent form.

Material

Propofol (Diprivan®, Astra-Zeneca, Zeneca Pharm) was the anesthetic agent used during colonoscopy. It was administered with Diprifusor TCI® (Astra-Zeneca, Zeneca Pharm) in the control group and with a self-controlled infusion pump (Alaris®) in the PCS group. Olympus CR 140 videocolonoscopes were used. All procedures were performed by two operators in order to limit interoperator variability. These two physicians with equivalent experience had performed endoscopic procedures for eight years.

Methods

Patients were monitored with a pulse oxymeter; a cardioscope, and an automatic blood pressure cuff. All patients received nasal oxygen (6 L/min).

CONTROL GROUP

Propofol was administered intravenously using the Diprifusor TCI® to achieve the concentration objective. Colonoscopy began when the anesthetist considered the patient was asleep. From this point the anesthetist alone controlled the propofol infusion, adapting the dose to assure adequate sedation and comfort for the patient. Other agents (morphinic agents for instance) could be used as needed. The anesthetist could also interrupt the propofol infusion before the end of the procedure in concert with the endoscopist. This constituted the “standard” protocol used in our unit.

PCS GROUP

The colonoscopy was started without anesthesia or premedication. An intravenous line was installed and patients self-administered propofol in 20-mg boluses as needed by pushing the pump’s delivery button. Minimal time between two bolus injections was 60 seconds, which corresponded to the time necessary to administer a bolus. During this lockout time, pushing the delivery button again had no effect. The patient was free to use the pump as desired. During the examination, the endoscopist and/or the nurse were free to advise the patient to push the delivery button, but the anesthetist did not intervene. A bip informed the endoscopist each time the patient self-administered a bolus. At each bip, the endoscopist interrupted progression of the colonoscopy while the bolus was being administered. If necessary, the endoscopist could ask the anesthetist to intervene at any time during the procedure. This situation was considered to constitute failure of PCS.

Data were recorded on a dedicated observation sheet. The patient completed the satisfaction VAS shortly after the examination (at least four hours after the end of the procedure). The patient was also asked to complete a questionnaire 48 hours and two weeks after the colonoscopy (Table I).

Statistical analysis

Preliminary data collected a few weeks before starting this study were used to determine the appropriate sample size. The objective was to assess the variability of the main outcome criterion. Fifteen patients who underwent colonoscopy using the standard sedation protocol completed the satisfaction VAS. Mean satisfaction was scored 95,2 mm with a standard deviation of 5.6. Hypothesizing equivalent variance of the main outcome criterion in the two groups, two-way analysis with 90% power and an alpha risk of 5% required a sample size of 70 patients to demonstrate a difference of 5 mm on the VAS.

Two persons not implicated in the present study used a random number table to prepare 50 envelopes numbered 1 to 50, each containing the sedation method to be used: i.e. either standard sedation or PCS. Twenty-two new envelops were then prepared because of two exclusions in the first randomization. When the final inclusion was achieved (availability of one of the two operators and signed consent forms), the contents of the envelop corresponding to the patient’s number of entry into the study was revealed in the presence of the patient.

EPI-INFO version 6-04 was used for statistical analysis. Patient characteristics were presented as descriptive variables and compared with standard tests (reduced deviation test for quantitative variables and chi-square test for qualitative variables). Mean satisfaction scores in the two groups were compared with Student’s t test. Comparisons for secondary outcome criteria were performed with appropriate tests (reduced deviation or chi-square) after checking for homogeneous variance.

Legal aspects

The study protocol and the information and consent forms were approved by the Auvergne ethics committee (CCP PB, Comité Consultatif de Protection des Personnes dans la Recherche Biomédicale). The voluntary subjects were informed of the objectives and the requirements for the present study and had the right to decline participation in the study or to withdraw at any moment.

Table I – Patient satisfaction questionnaires and willingness to undergo a new colonoscopy.

<table>
<thead>
<tr>
<th>Questionnaire to be completed by the patient 48 hours after the examination</th>
</tr>
</thead>
<tbody>
<tr>
<td>As regards the anesthesia method used during your colonoscopy, are you:</td>
</tr>
<tr>
<td>1-very satisfied</td>
</tr>
<tr>
<td>2-rather satisfied</td>
</tr>
<tr>
<td>3-rather dissatisfied</td>
</tr>
<tr>
<td>4-very dissatisfied</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Questionnaire to be completed by the patient 15 days after the examination</th>
</tr>
</thead>
<tbody>
<tr>
<td>If you would have to have another colonoscopy, would you</td>
</tr>
<tr>
<td>1-refuse a new colonoscopy</td>
</tr>
<tr>
<td>2-be willing to have a new colonoscopy performed under the same conditions</td>
</tr>
<tr>
<td>3-be willing to have a new colonoscopy but performed under different conditions</td>
</tr>
</tbody>
</table>

Results

Patients were included over a period of 41 weeks from December 2002 to September 2003. During this period 628 patients underwent colonoscopy. Among these patients, 226 also underwent an upper endoscopic procedure and were not eligible for inclusion. Among the 402 patients who underwent colonoscopy alone, 135 presented one or more non-inclusion criteria and the study protocol was not proposed to 94 others for uncontrollable reasons (procedure performed by endoscopists not participating in the study, N = 36; both of the investigator endoscopists unavailable, N = 19; investigators unavailable to perform inclusion, N = 39). Participating in the study was thus proposed to 173 patients: 101 patients declined participation (97 preferred standard sedation, three requested PCS, and one did not want sedation). Seventy-two patients gave their informed consent to participate in the study and were randomized to the two groups: 35 in the control group and 37 in the PCS group.

Two patients in the PCS group were excluded after inclusion. The first patient had been included by error; this patient had active inflammatory colitis and underwent an emergency procedure for bloody diarrhea. In the second patient colonoscopy revealed diverticular stricture in the descending colon which could not be crossed. Barium enema performed on the same day confirmed the stricture and the patient underwent surgery a few weeks later. In accordance with the study protocol, these two patients were excluded from the analysis.

Characteristics of the included patients

The characteristic features of the study population are presented in table II. The two groups were not significantly different as regards age, gender, history of colonoscopy, ASA score, history of colectomy or pelvic surgery, and body mass index (BMI).

Indications for colonoscopy

Indications for colonoscopy are summarized in table III. Abdominal pain was the only factor found to be more frequent in the control group.

<table>
<thead>
<tr>
<th>Indication for colonoscopy</th>
<th>PCS</th>
<th>Controls</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family history of colorectal cancer or polyps</td>
<td>12</td>
<td>7</td>
<td>ns</td>
</tr>
<tr>
<td>Personal history of polypectomy</td>
<td>8</td>
<td>7</td>
<td>ns</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>3</td>
<td>11</td>
<td>P = 0.03</td>
</tr>
<tr>
<td>Hematochezia</td>
<td>6</td>
<td>6</td>
<td>ns</td>
</tr>
<tr>
<td>Personal history of colorectal cancer</td>
<td>3</td>
<td>4</td>
<td>ns</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>1</td>
<td>6</td>
<td>ns</td>
</tr>
<tr>
<td>Constipation</td>
<td>4</td>
<td>2</td>
<td>ns</td>
</tr>
<tr>
<td>Anemia</td>
<td>2</td>
<td>1</td>
<td>ns</td>
</tr>
<tr>
<td>Inflammatory disease</td>
<td>1</td>
<td>0</td>
<td>ns</td>
</tr>
<tr>
<td>Other</td>
<td>2</td>
<td>8</td>
<td>ns</td>
</tr>
</tbody>
</table>

PCS: Patient-controlled sedation.

Success of the colonoscopic procedure

Colonoscopies which progressed to the cecum and during which the necessary diagnostic and therapeutic procedures were preformed were considered to be successful. All colonoscopies performed in the control group were successful. One procedure in the PCS group could not be completed. In this patient, the colonoscope was advanced to the right colon but the cecum was visualized at a distance. This was the third incomplete colonoscopy in this patient and failure was not attributed to the sedation method.

Failure of PCS

Propofol boluses failed to sedate pain in two patients in the PCS group (5.7%), necessitating a change in the sedation method. The anesthetist administered alfentanil (Rapifen®) intravenously and performed the necessary propofol injections until the colonoscopy was completed. PCS was considered to have failed. In accordance with the study protocol, these two patients were retained for the statistical analysis of the main outcome criteria. A satisfaction score of 0 mm was attributed to these two patients. There was no change the sedation method in the 33 other patients in the PCS group (94.3%).

Main outcome criterion

The mean satisfaction score on the VAS was 91.5 mm in the control group and 84.7 mm in the PCS group. The difference was not statistically significant (P = 0.24) and remained non-significant when the two PCS failures were excluded from the analysis (satisfaction score 89.9 mm in the PCS group, P = 0.42).

Colonoscopic procedure

At the end of the examination, each operator recorded the difficulty of the colonoscopic procedure (table IV). The two groups of patients were not statistically different for this parameter (table V). Mean time to reach the cecum was significantly shorter for colonoscopies in control group: 12 min (PCS) versus 8.2 min (controls), P = 0.004. However, the overall duration of the examination was not significantly different between the two groups: 19.3 min (PSC) versus 18 min (controls), P = 0.34.
Operator satisfaction with the sedation method was also evaluated with a VAS. It was better for "standard" sedation but not significantly. The results of the colonoscopy were considered normal for 30 patients (43%); presence of diverticulosis was noted in 22 patients (31.5%), 33 polyps were resected in 22 patients (31.5%), and biopsies were obtained in 13 patients (18.5%). There was no significant difference between the two groups for these results.

Differences between sedation methods

Maximal depth of sedation observed during the colonoscopy and the depth of sedation at the end of the examination were assessed by the anesthetist and or the nurse using a scale of 1 to 5 (table IV). The scores were significantly different between the two groups (table V): on average maximal sedation was lower in the PCS group and more patients in this group were fully awake at the end of the examination than in the control group. Mean dose of propofol delivered was 60 mg in the PCS group versus 248 mg in the control group (P < 0.001). Propofol dose in the control group ranged from 90 mg to 467 mg. The range was 0 mg to 160 mg in the PCS group. Half of the patients in the PCS group received > 60 mg propofol. Nine patients in this group (25.7%) did not use the infusion pump (0 mg propofol). The mean number of hours of surveillance was significantly lower in the PCS group and more patients in this group were fully awake at the end of the examination than in the control group.

Cardiorespiratory events

Thirteen episodes of low oxygen saturation (< 94% under 6 L O₂/min) were observed in the control group versus three in two patients in the PCS group. The difference was close to significance (P = 0.052). These episodes were managed by stimulating the patients or by subluxation of the mandible in two patients. There were 19 episodes of bradycardia, observed in nine patients in the control group (heart rate < 10% baseline rate) versus 16 episodes in six patients in the PCS group. The difference was not significant (P = 0.55). None of the patients in the PCS group required special care while one patient in the control group was given an injection of atropine.

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Colonoscopy without sedation

As indicated above, nine patients in the PCS group (25.7%) did not use self-controlled sedation. Eight were male patients who had had at least one prior colonoscopy and one female patient who underwent her first colonoscopy. Minimal VAS satisfaction in this subgroup was 88 mm. Eight of these nine patients responded to the questionnaires: seven were “very satisfied” but P = 0.06.

All would be willing to undergo another colonoscopy performed under the same conditions. In light of these results, we believe that considering patient satisfaction, it would be inappropriate to conclude that one or other of these two methods was superior in terms of clinical benefit.

In compliance with the study protocol, the two patients whose PCS was considered a failure were included in the analysis of VAS satisfaction (scored 0 mm for these two patients). This score was attributed because it would be reasonable to assume that if the endoscopist had continued the examination despite the intense pain experienced by these patients, they would have been dissatisfied with the examination. Not taking into account these two cases would have biased the analysis by considering only the favorable cases.

The results of the present study and those of five randomized studies of PCS during colonoscopy [11–15] are summarized in table VI. We used non-inclusion criteria applicable in an outpatient setting. This explains why only 43% of patients undergoing colonoscopy during the study period (173/402) were asked to participate in the study. Considering only these 173 eligible patients, the participation rate was satisfactory (72/173, 41.6%).
These figures are however quite different from others reported in the literature on PCS [11-15] where the participation rate was closer to 90%. This is an illustration of the French situation where “colonoscopy = general anesthesia” is well anchored in the minds of patients and physicians. Participation rate may also have been affected by insufficient organization in our unit patients since they met the endoscopist for the first time on the day of the endoscopic procedures, leaving little time to inform the patient and establish a relationship of confidence for participation in the study.

Theoretically, general anesthesia is used during colonoscopy to improve patient tolerance and acceptance. We thus considered that patient satisfaction with sedation was the most pertinent criteria for comparing PCS with standard anesthesia. Külling et al. [14] also used this criterion. It did not appear pertinent to evaluate pain since three prior studies [11, 14, 15] have demonstrated that patients in PCS groups experienced more pain but that it did not lead to their dissatisfaction. Considering the results of the ANGH study [16] devoted to patient opinion after colonoscopy, it appears essential to know whether patients would be willing to undergo another examination performed under the same conditions. However using “willing to undergo a future examination” as the main outcome criterion would have raised two problems: the risk of loosing patients to follow-up and the difficulty of determining the appropriate sample size. We then chose to evaluate patient satisfaction using a visual analog scale (VAS) as did Külling et al. [14]. Unlike a 5- or 6-point questionnaire, this method appeared to be more appropriate to demonstrate a small difference since responses were expected to be in the 70 mm to 100 mm range. The validity of this measurement method can be criticized: did patients score their satisfaction with overall care or with sedation alone? Such a hypothesis would be reinforced by the observation that, excepting the two failures, the VAS scores varied very little. This might reflect an influence of participation in the study which would reduce the impact of physical discomfort during the colonoscopy by improving other care factors: information, dialogue, well-experienced endoscopist, few people in the examination room. Salmon et al. [17] pointed out these factors after observing that the patient’s perception of colonoscopy is composed of three independent dimensions. These authors called the first dimension “satisfaction”, which corresponds to the patient's perception of overall care. The second dimension is emotional distress, and the third “physical discomfort”. According to these authors, management of pain, which corresponds to the physical discomfort dimension, does not improve the other components of the patient’s perception of their experience of colonoscopy [17].

Two other criticisms could be put forward: very early evaluation of satisfaction only a few hours after the examination and the presence of an investigator. This methodology enabled us to avoid loosing patients to follow-up and was warranted by the fact that use of a VAS required an explanation. It did lead to a partial evaluation of the impact of sedation since it did not take into account resumed activity nor compliant responses. To avoid these problems, we asked the patients to complete a questionnaire 48 hours after the colonoscopy. The VAS scores and the responses to the questionnaire were in agreement for 86% of patients.

Our findings show that PCS can be easily employed in routine practice. Only one colonoscopic procedure was not conducted to conclusion; its failure was not related to sedation. The procedure was completed in the two patients who experienced failure of the PCS. The total duration of the examination was slightly longer in the PCS group, but the difference did not reach the level of significance. PCS necessarily lengthened the examination time since for each bolus delivery, the endoscopist interrupted progression of the colonoscope while waiting for the propofol to produce its effect. But the objective was to demonstrate that the longer time is not excessive with PCS and in our opinion, the difference was negligible. The few extra minutes must be balanced against the time gained at the end of the examination for patients who are awake. The number of polyps resected was not different between the two groups. In conclusion, PCS did not appear to have any effect on the feasibility and the diagnostic yield of colonoscopy. Similar results have been reported by others [11-15].

One particularly important point is the fact that the two endoscopists who performed the colonoscopies in this study belong to a generation of physicians who learned the procedure at a time when deep sedation was the rule. This was one of the unknown factors in this study: can we perform colonoscopic procedures without deep sedation within a reasonable time without reducing the sensitivity (quality) of the examination? In fact, we found that learning the new technique was not a problem, so changing practices is a reasonable perspective. The endoscopists were more satisfied with “standard” sedation, but the difference did not reach significance.

The use of propofol as the only anesthetic agent without adjunction of morphine was required because the Diprifusor TC® is used in our unit for “standard” gastrointestinal endoscopic procedures and we wanted to compare two methods using the same product. The lock out interval was one minute, corresponding to the delay of administration of a propofol bolus. This interval is longer than reported in the literature but avoids pain at the injection point as it is often observed with propofol. Doses administered in the PCS group were 4-fold less than in the control group. This difference was very significant. In our opinion, it is one of the major points in favor of PCS. PCS lessens the need for anesthetic care during colonoscopy by adapting doses on an as needed basis.

Sedation may have been too deep in the control group, but there are no reference data in the literature concerning the appropriate propofol dose delivered by Diprifusor TC®. Nevertheless, the mean dose used in the PCS group was much lower than reported in studies using propofol alone: 157 mg and 73 mg respectively in two studies on sedation administered by endoscopists [18, 19].

Safety of PCS was not within the scope of our study. It was nevertheless noted that none of the patients in the PCS group required an intervention by the anesthetist. The number of episodes of bradycardia was not different between the two groups but the threshold chosen for study (10% below baseline heart rate) is not particularly pertinent clinically. It might have been more appropriate to consider only vagal reactions or drops in heart rate below 40 bpm. Thorpe et al. [20] focused on the safety of PCS in a study designed to evaluate the risk of overdosing. These authors asked 100 patients undergoing a surgical procedure with general anesthesia to put themselves asleep with a PCS pump delivering propofol. On average, the patients self-administered only 60% of the dose required to achieve deep sedation and only eleven patients were able to reach this level of sedation. The mean self-administered dose was 113 mg for women and 141 mg for men. The endoscopist was not in charge of the PCS in our study design, but the level of sedation in the PCS group and the self-administered doses observed suggest that this could be a possibility for certain patients. In our study, only two patients in the PCS group reached a sedation score of 5 (no response to light physical stimulation).

PCS enabled identification of patients who did not need anesthesia: one quarter of the colonoscopies performed in the PCS group were conducted without sedation and were well accepted by the patients. Earlier studies have not reported cases without sedation. Our results demonstrate that in France there is a population of patients who can undergo colonoscopy without sedation. According to the studies available in the literature, the
search for factors predictive of ability to undergo colonoscopy without sedation has been unfruitful: at the present time there is no way of predicting whether colonoscopy will be completed for a given patient and whether sedation will be necessary [21-24]. Conversely, other studies have demonstrated that patients who volunteer for procedures without sedation, or for sedation as needed, rarely effectively require sedation [25-27]. Our findings are well in line with this observation suggesting that a study of the characteristics of patients who volunteer for alternative forms of sedation could provide useful information.

Alternative methods of sedation such as PCS have been developed and promoted to change attitudes so that "anesthesia for all" will no longer be the rule. Endoscopists and anesthetists now know that they can propose colonoscopy with less sedation for certain patients. In this way, endoscopists could acquire a less traumatic technique and subsequently increase the number of patients volunteering for sedation as needed. At a time when mass screening is being promoted, colonoscopy can no longer retain the image of an invasive painful examination. In conclusion, our results demonstrate that the need for sedation is greatly overestimated in France and that our endoscopic practices can change. Some of our patients are willing to try the existing alternatives to general anesthesia. For these patients PCS is an attractive perspective.

REFERENCES