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Effect of conscious sedation with midazolam and fentanyl on the overall quality of colonoscopy: a prospective and randomized study

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ABSTRACT

Introduction: a prospective, randomized study was performed to assess the influence of conscious sedation on the overall quality of colonoscopy, simultaneously quantifying its effect on the scientific quality, perceived quality and patient safety.

Methods: patients referred for a colonoscopy were included in the study and were randomized to receive or not receive sedation. Demographic data, indication for colonoscopy, cecal intubation, introduction and withdrawal time, resected adenomas and complications during the exploration were collected. Thirty days later, a satisfaction questionnaire was performed (GHAA 9-me) and patients were asked about complications after the examination.

Results: a total of 5,328 patients were included, the average age was 62 ± 15.22 years, 47% were male, 3,734 were sedated and 1,594 were not sedated. The sedated patients had a shorter endoscope insertion time (7'20 ± 2'15 min *vs* 6'15 ± 3'12 min, $p < 0.019$), a higher rate of cecal intubations (96% *vs* 88%, $p < 0.05$), longer withdrawal time (7'20

± 2'15 min *vs* 6'15 ± 3'12 min, p < 0.01) and higher adenoma detection rates (22% *vs* 17%, p < 0.05). The use of sedation reduced discomfort during and after the exploration, without increasing the complications. The satisfaction questionnaire score was higher (23.6 ± 1.5 *vs* 16.6 ± 4.8, p < 0.001) in the sedated patients.

Conclusions: superficial sedation not only reduces patient discomfort but also improves the overall quality of the colonoscopy. Therefore, we must consider the use of sedation as an essential part of colonoscopy.

Key words: Sedation. Quality colonoscopy. Midazolam. Fentanyl. Adenoma detection rate. Cecal intubation rate. Perceived quality.

INTRODUCTION

All the changes applied when performing a medical procedure could influence the overall quality of the procedure. The use of sedation during colonoscopy is based on the need to reduce the discomfort experienced by patients during the exploration (1-3). With this aim, in recent years we have witnessed the progressive generalized use of sedation in endoscopy units (4-7). However, this change in the way that explorations are performed will influence all aspects of the exploration and therefore, the overall quality of the colonoscopy.

The effect that the use of sedation during colonoscopy has on the quality of the examination has been partially assessed, generally in a retrospective manner in several studies. Some studies have assessed the effect of sedation on scientific-technical quality (8-12), perceived quality (13-16) or safety (17-20). However, there are no studies that prospectively assess the effect of sedation on the overall quality of colonoscopy. To assess the effect of a medical intervention, such as the use of sedation on the overall quality of a colonoscopy, it is necessary to assess its effect on the different aspects of quality that are affected by the procedure (21). The use of sedation can directly affect three basic dimensions of colonoscopy quality: the scientific-technical quality, the perceived quality (patient satisfaction) and patient safety.

The purpose of this study was to prospectively assess the effect of superficial sedation with midazolam and fentanyl on the overall quality of colonoscopy. The study was performed under conditions of the usual clinical practice, measuring the effect that sedation has on scientific-technical quality, perceived quality and safety.

SUBJECTS AND METHODS

Six thousand consecutive outpatients referred to our Endoscopy Unit for a colonoscopy for the first time were invited to participate in this prospective, case-control study. The exclusion criteria were: patients who had previously undergone an endoscopy, under 18 years of age, an anesthetic risk higher than class III of the American Society of Anesthesiologists (ASA), an allergy to the drugs used (benzodiazepines and opioids), inability to answer the questionnaires, pregnant women and those on antiplatelet or anticoagulant treatment. The study protocol was approved by the HUNSC Ethics Committee and all patients who agreed to participate signed an informed consent form.

The patients were randomized into two groups, and the exploration was performed with conscious sedation (midazolam and fentanyl intravenous) or without sedation in a 2:1 ratio. The demographic data, patient clinical history and the indication of the colonoscopy were collected. All the examinations were performed by four endoscopists with extensive experience in both endoscopy and sedation (more than 7,000 colonoscopies each). During the endoscopy, the following parameters were recorded: if the colonoscopy reached the cecum, the time of introduction and removal of the endoscope, resected polyps, polyp location in the colon and complications. The degree of cleanliness of the colon was assessed according to the Boston classification. Good preparation was defined as a score of at least two points in each of the three sections of the colon and poor when there was at least one section with less than two points. Oxygen saturation and heart rate were monitored continuously from the beginning of the examination until the patient was discharged. Blood pressure was measured at the beginning of the examination, upon completion of the introduction of the endoscope, at the end of the procedure, before discharge and at any time deemed necessary according to the clinical situation of the patient. Patients were discharged

from the Endoscopy Unit upon reaching a score of 9 on the Aldrete scale (22). Patients completed a survey about the discomfort experienced during the test and the recovery period before leaving the Endoscopy Unit.

The resected polyps were assessed based on the pathology report. The patients were interviewed via telephone by non-study personnel (call-center) 30 days after the colonoscopy, to determine the complications that had occurred since discharge from the unit and to assess patient satisfaction with the exploration. Patient satisfaction was quantified using the GHAA 9-me endoscopy satisfaction questionnaire from the ASGE (23), which was previously translated and validated into Spanish by our group (24,25).

The scientific-technical quality of each exploration was assessed according to six indicators. This included three technical indicators of the process: the percentage of colonoscopies that reached the cecum (cecal intubation rate), colonoscopy introduction time and withdrawal time. Three indicators of the results were also assessed: the percentage of patients with at least one adenoma (adenoma detection rate), the percentage of patients with at least one advanced adenoma (advanced adenoma rate) and the percentage of patients with at least one serrated polyp proximal to the sigmoid (rate of serrated polyps). Hyperplastic polyps of the sigmoid colon and rectum were also ruled out. The indicator of colon cleanliness was used as a control variable between groups, as colon cleanliness is not influenced by sedation.

The perceived quality or patient satisfaction was assessed according to the following parameters: the total score of the satisfaction questionnaire (scored from 0 to 28), the overall score given by each patient for the examination in item 7 of the questionnaire (scored from 0 to 4) and the percentage of patients who rated the examination as excellent (4 points on item 7 of the questionnaire) (15,25). The safety of each test was assessed according to the system previously used in other studies (18). Early complications (those during the exploration and recovery period) and late complications (those occurring within 30 days after the examination) were determined and categorized as major when medical attention was required and minor when they were resolved without medical attention. The study protocol was approved by the HUNSC Ethics Committee and all patients who agreed to participate signed the

informed consent.

Statistical analysis

The statistical analysis was performed using the statistical package for social sciences (SPSS version 17.0, SPSS Inc., Chicago, Illinois, USA). The normal distribution of the sample data was determined using the exploration and descriptive functions of SPSS. The time of intubation and removal of the endoscope are expressed as the mean ± standard deviation. Comparisons between quantitative variables were performed using the Student's t-test. The indication for the colonoscopy, rate of cecal intubation, rates of adenomas, advanced adenomas and serrated polyps, distribution of polyps in the three sections of the colon and early and late complications are expressed as percentages with the corresponding 95% confidence intervals (95% CI). Comparisons between proportions were performed using the Chi-square test. A p value < 0.05 was considered as statistically significant.

RESULTS

Study in the Endoscopy Unit

Patient selection

A total of 672 patients refused to participate or were excluded from the study. Therefore, 5,328 patients were finally included with a mean age of 62 ± 15.22 years and 47% were male. Of all the endoscopies, 3,734 were performed with sedation and 1,594 without sedation. As shown in table 1, there were no differences between the two groups in terms of age, sex, anesthetic risk ranked according to the classification scheme of the ASA, indications of colonoscopy or the degree of colon cleanliness.

Technical scientific quality

As shown in table 2, the cecal fundus was reached significantly more frequently in colonoscopies performed with sedation (96%, 95% CI: 95-97 *vs* 88%, 95% CI: 86-89, p < 0.001). This improvement occurred equally in males and females, in patients older and younger than 50 years and with all four endoscopists.

The colonoscopy insertion time was significantly lower during endoscopies performed with sedation than in those without sedation (6'15 ± 3'25 min *vs* 8'3 ± 4'14 min; p < 0.05). On the other hand, the withdrawal time was significantly greater in the group of patients with sedation than in the group without sedation, (8'20 ± 2'15 min *vs* 5'35 ± 3'12 min; p < 0.01). These differences occurred similarly regardless of the sex and age of the patients and the endoscopist who performed the examination.

The percentage of patients with at least one adenoma (adenoma detection rate: 22%, 95% CI: 20-23 *vs* 17%, 95% CI: 15-19, p < 0.05), some advanced adenomas (advanced adenoma detection rate: 8%, 95% CI: 7-9 *vs* 4.3%, 95% CI: 3-5, p < 0.05) or serrated polyps (serrated polyp detection rate: 1.9%, 95% CI: 1-3 *vs* 0.6%, 95% CI: 0.2-0.9, p = 0.05) was significantly higher in the group of endoscopies performed with sedation. This improvement in adenoma resection rates occurred similarly regardless of the sex and age of the patients and the indication for the colonoscopy.

A comparison of the distribution of resected adenomas in the colon showed that the improvement in the rate of adenomas in sedated patients occurred at a higher rate in right colon adenomas and there was no change in the remaining sections of the colon.

Early complications

Table 2 shows the complications that occurred during the examinations and until the patients were discharged from the Endoscopy Unit. No differences were found in major complications between the two groups. There were three hemorrhages in the sedated patient group and two hemorrhages and one perforation among the non-sedated patients. These six patients required medical attention and only one from each group was admitted due to a hemorrhage in the sedated group and a perforation of the non-sedated group. No major cardiorespiratory complications were reported.

Bradycardia (12%, 95% CI: 11-13 *vs* 7%, 95% CI: 6.7-7.2, p < 0.05) and desaturations (10%, 95% CI: 9-11 *vs* 2%, 95% CI: 1.8-2.1, p < 0.01) were significantly more frequent among patients who underwent sedation. These patients recovered without specific treatment and were therefore classified as minor complications. On the other hand, pain during the examination (8%, 95% CI: 7-9 *vs* 85%, 95% CI: 83-87, p < 0.000) was significantly more frequent in patients without sedation.

Telephone survey (30 days after the examination)

A total of 959 patients did not respond to the telephone survey; 612 could not be located and 347 did not want to answer the survey. Of the 4,369 who responded (80% of those initially included), 3,099 (83%) were from the colonoscopy group performed with sedation and 1,270 (79%) from the group without sedation.

Perceived quality or satisfaction

The scores of the patient satisfaction questionnaire in the sedation group were significantly higher than those of the no sedation group (Table 3) in several parameters. These included the total score of the questionnaire (23.6 ± 1.5 *vs* 16.6 ± 4.8, $p < 0.001$), the general assessment of the test, i.e. item number 7 (2.84 ± 0.852 *vs* 1.1 ± 1.9, $p < 0.001$), and the percentage of patients who gave an excellent score for the test (56%, 95% CI: 54-58 *vs* 3%, 95% CI: 2-4, $p < 0.001$).

Late complications

Table 3 shows the late complications after the examinations. No major complications were recorded within 30 days after the examination. After the test, the patients without sedation reported abdominal pain (2.5, 95% CI: 2-3 *vs* 13%, 95% CI: 11-15, $p < 0.05$) and abdominal distension (3%, 95% CI: 2-4 *vs* 18%, 95% CI: 16-20, $p < 0.05$). They also returned to their primary care physician due to these symptoms (0.48%, 95% CI: 0.2-0.7 *vs* 3.6%, 95% CI: 3-5, $p < 0.001$) significantly more frequently than patients in the no sedation group.

DISCUSSION

Although in recent years there has been a large increase in the use of sedation in colonoscopy to reduce the discomfort of the examination, currently, a large number of colonoscopies are performed without sedation (4,5,26). Our data demonstrate that the use of sedation during colonoscopy not only reduces the discomfort suffered by patients but is also a fundamental determinant of the global quality of routine colonoscopy. Sedation improves the three dimensions of quality: scientific-technical

quality, safety and patient satisfaction. Therefore, the use of sedation should become mandatory when performing a colonoscopy.

In our study, the use of sedation during colonoscopy resulted in a shorter time of introduction of the endoscope, a greater cecal intubation rate, a longer withdrawal time and higher adenoma, advanced adenoma and serrated polyp detection rate. There was a very significant decrease in patient discomfort, without increasing the major complications of the examination. In addition, the use of sedation translated into higher rates of patient satisfaction with the care received.

In our opinion, these results show that sedation allows the endoscopist to perform the maneuvers for endoscope insertion more calmly, allowing them to reach the cecum more quickly, with less discomfort for the patient. In this way, a slower withdrawal can be performed with a more thorough exploration, which results in a higher rate of adenoma detection. In contrast, non-sedated patients experience a very significant increase in discomfort, with a longer insertion time and a lower rate of cecal intubation. This situation likely leads the endoscopist to perform a faster removal with a less careful exploration, which translates into a lower rate of adenoma detection.

Most studies have found that the use of sedation improves the rates of cecal intubation and resected adenomas (8-10). However, the largest study conducted to date by Bannert et al. did not find any improvement (11). This study reported that the use of sedation increased the rate of cecal intubation in both males and females, which did not translate into changes in the adenoma detection rate. On the contrary, our data support the idea that the use of sedation significantly increases both the rate of cecal intubation and the adenoma detection rate. We believe that the reason for these differences is due to the population differences. Bannert et al. used data from a CRC screening program. This included colonoscopies performed by selected endoscopists, in patients over 50 years of age with a positive fecal occult blood test. On the other hand, the patients in the screening program chose whether they wanted sedation, which introduced a selection bias. Our patient cohort reflects the daily work of an endoscopy unit and patients were randomized to receive or not receive sedation.

The adenoma detection rate obtained in our study may seem a little low (22% in sedated patients *vs* 17% in the non-sedated patients) with respect to other case series.

However, we must take into account that it is an open endoscopy unit and endoscopy cases are referred from both specialized care and primary care. Furthermore, 46% of our patients were younger than 50, which may explain our findings. In fact, the adenoma detection rate in patients referred for CRC screening increased to 35% in the non-sedated patients and 41% in the sedated patients.

The increase in adenoma detection rate secondary to the use of sedation could occur at the expense of the detection of tiny polyps and therefore, without clinical importance. However, the use of sedation significantly increased the rate of advanced adenoma and serrated polyp detection. Thus, the improvement obtained in the rate of adenoma detection has a clear clinical relevance.

When comparing the distribution of the resected polyps, we verified that the improvement of the adenoma detection rate occurred at the expense of adenomas of the right colon. The rate was 13% in sedated patients *vs* 6% in non-sedated patients, and there were no differences in the rest of the sections of the colon. We think that this improvement is due to a more careful exploration of the right colon, thanks to the lesser discomfort suffered by sedated patients. This is important as we know that interval cancers in CRC screening programs have been linked to the development of lesions in the right colon (27,28), especially with serrated lesions (29,30).

The use of sedation was not accompanied by changes in the rate of major complications or those related to the endoscopy (perforation, hemorrhage, etc.) or sedation (cardiorespiratory events that required medical attention). In contrast, there were differences in minor complications. Cardiorespiratory alterations during the exploration (hypotension, bradycardia and hypoxemia) were significantly more frequent among sedated patients. However, these alterations did not have clinical repercussions and did not require any medical intervention. Furthermore, they were reflected in the rest of the quality indicators (cecal intubation rate, adenoma detection rate, satisfaction questionnaire score).

Discomfort during the examination and the following days was significantly more frequent among the non-sedated patients. These minor complications were of clinical importance as they reflected both the scientific and technical quality (lower cecal intubation rate and adenoma detection rate) and the perceived quality (lower scores

on the satisfaction questionnaire). On the other hand, patients who did not receive sedation more frequently required medical assistance by their primary care physician during the days after the examination.

As in previous studies (13-16), our data show that the use of sedation significantly improves the degree of patient satisfaction with the assistance received. These data are of great importance for the application of population screening programs for CRC. The greater the number of patients satisfied after colonoscopy, the greater the acceptability of colonoscopy by the general population. This ultimately leads to an increased participation in these programs (15).

This study was carried out in a single center, which may limit the generalization of our conclusions. However, the high number of patients and the homogeneity of the results among the four endoscopists implies that the results of this study can be extrapolated to other centers. The endoscopists who participated in the study have extensive experience in this type of exploration. However, it should be taken into account that these are endoscopists accustomed to working with sedation, which could have negatively affected the results of the non-sedated group. Thus, increasing the difference between the two groups. This aspect may limit the interpretation of our results.

In recent years, the use of deep sedation with propofol has been generalized in colonoscopy. It is possible that deep sedation improves the results obtained with classic superficial sedation with benzodiazepines and opioids that were used in this study (31,32). Therefore, it would be necessary to compare the effect of both sedation methods on the overall quality of colonoscopy in order to corroborate this hypothesis

In summary, the use of superficial sedation with midazolam and fentanyl not only reduces patient discomfort but also improves the overall quality of colonoscopy by improving scientific-technical results and patient satisfaction, without compromising safety. Therefore, we must consider the use of sedation as an integral part of colonoscopy, almost compulsory.

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Table 1. Group characteristics

Groups characteristics		Non-sedated patients (n = 1,594)	Sedated patients (n = 3,734)	p
Age		61 ± 16	62 ± 18	n.s.
Sex	Males	806 (51%; 95% CI: 48-54)	1,698 (46%; 95% CI: 44-47)	n.s.
	Females	788 (49%; 95% CI: 45-52)	2,036 (54%; 95% CI: 52-55)	n.s.
Anesthetic risk	ASA I	638 (40%; 95% CI: 37-43)	1,568 (42%; 95% CI: 40-44)	n.s.
	ASA II	542 (34%; 95% CI: 31-37)	1,121 (30%; 95% CI: 28-31)	n.s.
	ASA III	414 (26%; 95% CI: 23-29)	1,045 (28%; 95% CI: 26-29)	n.s.
Indications of colonoscopy	Bleeding	351 (22%; 95% CI: 20-24)	933 (25%; 95% CI: 23-26)	n.s.
	Anemia	223 (14%; 95% CI: 12-16)	485 (13%; 95% CI: 11-14)	n.s.
	Abdominal pain	319 (20%; 95% CI: 18-22)	635 (17%; 95% CI: 16-18)	n.s.
	CCR screening	271 (17%; 95% CI: 15-19)	709 (19%; 95% CI: 18-20)	n.s.
	Diarrheas	223 (14%; 95% CI: 12-16)	448 (12%; 95% CI: 11-13)	n.s.
	Constipation	79 (5%; 95% CI: 4-5)	262 (7%; 95% CI: 6-8)	n.s.
	Others	128 (8%; 95% CI: 6-10)	262 (7%; 95% CI: 6-8)	n.s.
Sedation used	Midazolam	----	3.5 ± 0.5 mg e.v.	---
	Fentanyl	----	0.11 ± 0.03 mg e.v.	---
Explorations carried out for each endoscopist	Endoscopist nº 1	556 (32%)	1,202 (68%)	---
	Endoscopist nº 2	431 (30%)	1,006 (70%)	---
	Endoscopist nº 3	341 (29%)	834 (71%)	---
	Endoscopist nº 4	266 (28%)	692 (72%)	---
Degree of colon cleanliness	Good preparation	1,307 (82%; 95% CI: 80-84)	3,136 (84%; 95% CI: 83-85)	n.s.

Sex, anesthetic risk according to the ASA classification, indications for colonoscopy and the degree of cleanliness of the colon are expressed as the total number of patients, the corresponding percentage and the 95% confidence interval. The sedation used is expressed as the average dose with the standard deviation. The colonoscopies

performed by each endoscopist are shown as the total number and the corresponding percentage.

Table 2. Exploration data

Exploration data		Non-sedated patients (n = 1,594)	Sedated patients (n = 3,734)	p
Colonoscopy introduction time	Total group	8.30 ± 4.14	6.15 ± 3.25	< 0.05
	Males	7.45 ± 2.45	5.35 ± 2.38	< 0.05
	Females	8.35 ± 4.25	6.32 ± 4.15	< 0.05
	Age ≤ 50 years	7.25 ± 2.18	5.42 ± 3.18	< 0.05
	Age > 50 years	8.40 ± 3.18	6.38 ± 3.32	< 0.05
Colonoscopy withdrawal time	Total group	5.35 ± 3.12	8.20 ± 2.15	< 0.05
	Males	5.12 ± 3.47	8.15 ± 2.10	< 0.05
	Females	5.19 ± 2.34	8.25 ± 2.28	< 0.05
	Age ≤ 50 years	4.42 ± 4.41	8.16 ± 2.31	< 0.05
	Age > 50 years	5.35 ± 4.41	8.22 ± 2.09	< 0.05
Complete colonoscopies (cecal intubation)	Total group	1,403 (88%; 95% CI: 86-89)	3,585 (96%; 95% CI: 95-97)	< 0.05
	Males	766 (94%; 95% CI: 93-95)	1,659 (98%; 95% CI: 97-99)	< 0.05
	Females	637 (81%; 95% CI: 79-83)	1,926 (95%; 95% CI: 94-96)	< 0.01
	Age ≤ 50 years	711 (90%; 95% CI: 89-91)	1,747 (97%; 95% CI: 96-98)	< 0.05
	Age > 50 years	692 (86%; 95% CI: 84-88)	1,838 (95%; 95% CI: 93-96)	< 0.05
Adenomas detection rate (ADR)	ADR	271 (17%; 95% CI: 15-19)	821 (22%; 95% CI: 20-23)	< 0.05
	Advanced adenoma detection rate	68 (4.3%; 95% CI: 3-5)	298 (8%; 95% CI: 7-9)	< 0.05
	Serrated polyp detection rate	10 (0.6%; 95% CI: 0.2-0.9)	71 (1.9%; 95% CI: 1-3)	< 0.05
	ADR in male patients	185 (23%; 95% CI: 20-25)	485 (28%; 95% CI: 26-30)	< 0.05
	ADR in female patients	86 (11%; 95% CI: 8-13)	336 (17%; 95% CI: 15-19)	< 0.05
Adenomas detection rate (ADR) depending on the indication of the colonoscopy	Bleeding	55 (16%; IC: 13-18)	193 (21%; IC: 18-24)	< 0.05
	Anemia	59 (26%; IC: 22-28)	160 (33%; IC: 29-37)	< 0.05
	Abdominal pain	24 (7.5%; IC: 5-9)	67 (11%; IC: 9-13)	< 0.05
	CCR screening	95 (35%; IC: 29-38)	290 (41; IC: 39-44)	< 0.05
	Diarrheas	27 (12%; IC: 8-14)	72 (16%; IC: 13-19)	< 0.05
	Constipation	4 (4%; IC: 2-5)	20 (8%; IC: 5-11)	< 0.05
	Others	7 (5%; IC: 1-6)	19 (7%; IC: 4-10)	< 0.05
Distribution of adenomas in the colon	Total number of adenomas	677	2,380	
	Rectum	95 (14%; 95% CI: 11-17)	285 (12%; 95% CI: 11-13)	n.s.
	Sigmoid colon	305 (45%; 95% CI: 41-49)	998 (42%; 95% CI: 40-44)	n.s.
	Descending colon	162 24%; 95% CI: 21-27)	502 (21%; 95% CI: 19-23)	n.s.
	Transverse colon	74 (11%; 95% CI: 9-13)	286 (12%; 95% CI: 11-13)	n.s.
	Ascending colon	41 (6%; 95% CI: 4-8)	308 (13%; 95% CI: 12-14)	< 0,05
Early complications	Bradycardia	111 (7%; 95% CI: 6.7-7.2)	448 (12%; 95% CI: 11-13)	0,05
	Hypotension	30 (1.9; 95% CI: 1.7-2.0)	74 (2%; 95% CI: 1-2)	n.s.
	Desaturations	32 (2%; 95% CI: 1.8-2.1)	373 (10%; 95% CI: 9-11)	< 0,05
	Discomfort (pain/distension)	1355 (85%; 95% CI: 83-87)	299 (8%; 95% CI: 7-9)	< 0,05
	Bleeding	2 (0.1%; 95% CI: 0.05-0.14)	3 (0.08%; 95% CI: 2-3)	n.s.
	Perforation	1 (0.05%; 95% CI: 0.01-0.08)	0 (0%)	n.s.
	Medical attention required	3 (0.2%; 95% CI: 0.08-0.3)	3 (0.08%; 95% CI: 0.05-0.1)	n.s.
	Hospitalization	1 (0.05%; 95% CI: 0.01-0.08)	1 (0.03%; 95% CI: 0.01-0.1)	n.s.

The colonoscopy insertion and removal time is expressed as the mean with the standard deviation. The cecal intubation, adenoma rates, adenoma rates depending on the indication of colonoscopy, distribution of adenomas in the colon and rate of early complications are expressed as the total number with the corresponding percentage and the 95% confidence interval.

Table 3. Result of the telephone survey performed after 30 days

Telephone survey (30 days after examination)		Non-sedated patients (n = 1,270)	Sedated patients (n = 3,099)	p
Late complications	Abdominal pain	162 (13%; 95% CI: 11-15)	77 (2.5%; 95% CI: 2-3)	< 0.05
	Abdominal distension	229 (18%; 95% CI: 16-12)	93 (3%; 95% CI: 2-4)	< 0.05
	Bleeding	5 (0.4%; 95% CI: 0.1-0.7)	8 (0.3%; 95% CI: 0.1-0.4)	n.s.
	Fever	2 (0.1%; 95% CI: 0.05-0.15)	3 (0.08%; 95% CI: 0.05-0.09)	n.s.
	Constipations	215 (17%; 95% CI: 15-19)	465 (15%; 95% CI: 14-16)	n.s.
	Diarrhea	35 (2.7%; 95% CI: 2.4-2.9)	62 (2%; 95% CI: 1.5-2.5)	n.s.
	Medical attention required	46 (3.6%; 95% CI: 3.3-3.7)	38 (0.48%; 95% CI: 0.4-0.5)	0.05
	Hospitalization	0 (0%)	0 (0%)	n.s.
Patient satisfaction questionnaire	Total score of the questionnaire	16.6 ± 4.8	23.6 ± 1.5	< 0.05
		1.1 ± 1.9	2.84 ± 0.852	< 0.05
	Assessment of colonoscopy (item 7)	38 (3%; 95% CI: 2-3)	1,735 (56%; 95% CI: 54-58)	< 0.05
	Percentage of excellent (item7)			

Late complications are expressed as the number of patients, percentage and the corresponding confidence interval. The total score of the satisfaction questionnaire and the score of the colonoscopy (item 7 of the questionnaire) are expressed as the mean with the standard deviation. The percentage of excellent scores are expressed as the total number, the percentage and the corresponding confidence interval.

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