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A descriptive monitoring study of a non-anesthetist sedation quality program

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ABSTRACT

Introduction: sedation substantially improves the quality of digestive endoscopy procedures but may result in severe complications.

Methods: a joint commission-based multidisciplinary protocol was used to define a protocol for sedation by non-anesthesiologists. ASA 4 patients were excluded, as well as patients with a difficult airway, complex procedures and deep sedation. Quality based on the analysis of 9 indicators were monitored. Incomplete procedures were also monitored in order to assess efficacy.
Results: patient safety was established based on a very low incidence of complications and a rate of respiratory events of 1.07. Furthermore, a low rate of hypotension and bradycardia was found, as well as a low rate of pain, either during or after endoscopy and an incidence of unexpected admissions lower than 0.5%. The quality indicators measured reflect the evolution of the results of the program.

Conclusions: ongoing sedation program monitoring in endoscopy allows the control of different quality dimensions and the implementation of steps for process improvement.

Key words: Sedation. Safety. Quality. Endoscopy.

INTRODUCTION
Although sedation improves endoscopy tolerance (1) and should therefore be offered to all patients before any endoscopic procedure (2,3) it represents a risk for patients and requires that the process is designed to minimize the development of potentially harmful adverse events. This risk prompts the development of programs to improve patient safety and to increase the quality parameters of the procedure. To meet this goal, all professionals that play a role in digestive endoscopy (gastroenterologists, anesthesiologists, nurses) must be involved in the development of multidisciplinary healthcare protocols. These are needed to define the process, establish improvement measures and to assess outcomes that use monitoring systems, as scientific societies recommend that quality be evaluated and improved on an ongoing basis (4,5).

The follow-up of implemented measures may be accomplished using monitoring systems based on quality indicators, which represent the basic units in a monitoring system (6,7). Several gastroenterology-related institutions recommend that quality-monitoring indicators be established. However, compliance extent is variable. Thus, Fernández Urien et al. (8) showed that compliance with quality indicators in Spain is low and only a minority of units comply with the indicators recommended in the literature (9-13). The primary goal of this study was to demonstrate the safety of the protocol designed for the sedation of patients undergoing digestive endoscopy based on the annual analysis of indicators. The secondary
endpoint was to assess the complications arising from endoscopic procedures.

PATIENTS AND METHODS
This was a prospective study from October 2010 to August 2016 and patients signed an informed consent form for the anonymous surrender of their data. The study complies with applicable EQUATOR Network guidelines and was endorsed by the Galician Ethics Committee (Comité Autonómico de Ética de la Investigación). A task force was set up with gastroenterology, anesthesiology and nursing staff in order to develop a hospital sedation protocol (including moderate and deep sedation). In a second stage (Stage 2) (Fig. 1), training was given to specialists. The results were analysed during the third stage, which spanned over almost six years. Following this analysis, measures for improvement were implemented (fourth stage). For indicator selection, a thorough review of the literature was performed (9-14) which resulted in a group of indicators with software-driven automated data collection.

Working protocol
Sedation levels were those defined in the European Society of Anaesthesiology (ESA) protocol (16):

- Sedation level 1: patient fully awake.
- Sedation level 2: drowsiness. Effective spontaneous ventilation.
- Sedation level 3: patient apparently asleep, responds to verbal stimuli.
- Sedation level 4: patient apparently asleep, responds to physical stimuli.
- Sedation level 5: patient asleep, comatose, does not respond to physical stimuli.

Sedation goals for non-anesthesiologists
In sedation and/or analgesia as administered by NAs, vital protective reflexes should not be abolished. One should aim to reach sedation level 3 at most.

Inclusion criteria for sedation by non-anesthesiologists (NAs)
— Stable ASA 1, 2, 3 patients.
— Minor diagnostic or therapeutic endoscopic procedures.

Patients unfit for sedation by NAs
— Patients who need treatment or intensive care (ASA 4).
— Complex or long-duration endoscopic techniques (ERCP or EUS).
— Deep sedation required.
— Patients with difficult airway or conditions that may render airway management difficult.

Presedation assessment
Presedation assessment was mandatory for all patients. A clinical decision aid system was incorporated in this setting (the software flagged patients where gastroenterologist-administered sedation was contraindicated).

Safety checklist
This was based on WHO recommendations, the safety program checklist was adapted to sedation procedures by non-anesthesiologists (17). The modified Aldrete score (18,19) was used for discharge assessment and patients were contacted by telephone for reassessment after 24 hrs. The same person called in every instance.

Training
Non-anesthesiologists must be properly trained to manage situations where the sedation level is inadvertently deepened. To this end, a complete training program was developed that included both theory and hands-on practice. Training was given by the anesthesiology service, our program was similar to that issued by the European Endoscopy Society (20).

Drugs
Only midazolam (repeat 1-2-mg doses) and fentanyl (50-75 mcg) were used, with doses adjusted to age and any underlying condition. The gastroenterologist must indicate the
appropriate procedure and estimate its duration via an assessment of patient type and therefore schedule no sedation, sedation by a non-anesthesiologist, or sedation by an anesthesiologist. The gastroenterologist decides the type of sedation to be used regardless of the location used and a nurse administers sedation and monitors the patient (nurses received the same training program).

PROCESS MONITORING: INDICATORS

Presedation indicators

*Indicator 1:* patient without an appropriately signed informed consent form on arrival to the endoscopy room.

*Indicator 2:* patient sedated off-protocol (patients with an indicated sedation by anesthesiologist).

*Indicator 3:* presedation checklist completed.

Indicators during endoscopy

*Indicator 4:* patient with a deep level of sedation (patients with a sedation level above 3 anytime during the procedure).

*Indicator 5:* patient with cardiorespiratory complications during the procedure.

*Indicator 6:* pain during and after the procedure.

Post-sedation indicators

*Indicator 7:* outpatient with an unexpected admission.

*Indicator 8:* patient with an excellent satisfaction level.

*Indicator 9:* procedure called off before starting.

Quality was assessed based on the compliance with indicators, each was previously defined and incorporated into the hospital protocol.

INFORMATICS DEVELOPMENT
Data recording and processing was used for process monitoring (21,22). A specific software was developed with four key premises:

— Development of an electronic health record to fully replace the paper-based one.
— Data coding to facilitate data exploitation.
— Addition of protocols to provide an electronic clinical decision aid in order to reduce variability in the clinical practice.
— Mandatory completion of key fields so that further fill-in or form saving is thwarted in the presence of incomplete data.

STATISTICAL ANALYSIS
Quantitative variables are expressed as the mean ± SD when following a normal distribution (Kolmogorov-Smirnov test) and as the median ± IQR when the distribution was not normal. Qualitative variables are expressed as frequencies, followed by percentage between parentheses. The multivariate analysis of risk factors associated with complicaciones during endoscopy was performed using a stepwise multivariate logistic regression model. A p-value < 0.05 was considered to be significant. The statistical analysis was performed using the Windows SPSS v.15 (SPSS Inc., Chicago, IL, USA) or R v.3.0.1 (R Development Core Team, 2013, Vienna, Austria) software package.

RESULTS (Table 1)
Sample description
Our hospital currently has three endoscopy rooms that are active during the morning and evening shifts, the third room has been in operation for one year now. At present 7 gastroenterologists are available and there are no specialty trainees.

Patient distribution
30,305 digestive endoscopy procedures were scheduled during the data collection period from October 2010 to August 2016; 12,317 procedures involved sedation either by gastroenterologists (9,530 patients) or anesthesiologists (2,787 patients, who were excluded from the present study).
Drugs
Only midazolam and fentanyl were used as sedatives. With regard to midazolam, the mean total dosage was $3.34 \pm 1.22$ mg and the mean number of doses was $1.95 \pm 1.06$. With regard to fentanyl, the mean total dosage was $87.16 \pm 36.6$ mcg and the mean number of doses was $1.83 \pm 0.89$. The mean body weight was $71.65 \pm 13.94$ kg and the mean procedure duration was $22.89 \pm 12.85$ min.

Quality indicators
Presedation indicators (Fig. 1)
The incidence density for each indicator is shown in figures 1-3. With respect to indicator 1, only 20 (0.2%) procedures were called off due to a lack of informed consent. The rest had correctly signed their consent in due time. "Righted consent" was defined as that which was unavailable at the onset of the procedure but was marked as "signed" in the medical records. A significant decrease in righted consents was found over the study period. Patients sedated off-protocol were kept below 1.5%, as shown in figure 1. Presedation checklists were reviewed in all cases (100%), with a very high percentage of completed records (>98%).

Indicators during sedation (Fig. 2)
The number of patients with inappropriate sedation levels (above 3 in the ESA scale) was gradually reduced from 7.4% at study onset to 1.6% at the end of the study. Table 2 shows the incidence of complications observed during and after endoscopy, the rate of hemodynamic complications was higher than that of respiratory complications. The risk factors associated with common complications were included in the multivariate analysis (Table 3). With regard to pain during the procedure, the rate of suspensions due to poor tolerability reached 4.1%, while the incidence of pain was slightly higher at 4.7%. Figure 2 also shows that the incidence of pain after endoscopy gradually decreased, even to 6% at some time points, although 3.06 of patients required painkillers after sedation recovery.

Postsedation indicators
As shown in Figure 3, the percentage of patients unexpectedly admitted to hospital following sedation remained below 0.5%. The most common reasons for an unexpected hospitalization after digestive endoscopy included pain, nausea and vomiting. Although, the incidence of such admissions was very low. Furthermore, the satisfaction level was very high from the second year of the study onwards, over 90% scored their satisfaction as "excellent". Finally, the rate of procedures that were not performed reached 9.85% during some periods, the most common cause was a failure of the patient to attend the scheduled test (70.37% of cancelled procedures).

**DISCUSSION**

Our results show that sedation for digestive endoscopy can be monitored and improved while securing the objectives set forth at the start of the program, such as a low complication rate within the range established by scientific publications (safe sedation) and a high level of patient satisfaction. Our protocol was designed to provide ongoing improvements in care by modifying the whole sedation process based on compliance with safety tenets, as established by the Joint Commission (4). Thus, a care process was devised that focused primarily on patient-centered health quality improvement and a search for greater safety, scientific-technical quality and patient satisfaction. Based on this, we set out to design a process with a multidisciplinary basis that prioritized safety.

With regard to informed consent (first indicator), this is mandatory in Spain (3,15) although sedation for digestive endoscopy may be administered at times without informed consent. Thus, only 18% of endoscopy units usually have a properly signed consent form that is available from the start and over 30% of units have no written informed consent available at all (8). In our study, all patients had signed an informed consent form (our hospital has an electronic version implemented, also specifying who will administer sedation), but this was still unavailable when some of the patients arrived to the endoscopy room (hence the term "righted").

With regard to the second indicator, some authors include a preoperative assessment as a key indicator for the analysis of sedation quality while acknowledging this is a challenging
parameter to measure (15). Since our software requires a complete preanesthetic assessment before sedation onset, 100% of patients will comply with this. Thus, we decided to monitor the number of patients included in the group of gastroenterologist-administered sedation who should had been cared for by an anesthesiologist, as our software includes clinical decision aids and managed to keep this indicator under 2% over the entire study period. We could not find any reports on this subject that allowed a comparison with our results.

Sedation checklist use is far more widespread in the surgical setting that are based on World Health Organization guidelines (17). Most reports derive from surgical settings (23) and few references deal with checklist implementation in digestive endoscopy units. In addition to our hospital, some other studies of specific checklist implementation may be found in Spain, starting in 2010. The adherence is above 85% but varies according to each individual practitioner (24). In our study, checklist compliance was always above 90%. However, standards in a safety process must approach 100%. Many studies do not report target sedation level (intended sedation level), which limits conclusions. Whether the actual level obtained was beyond the target level cannot be assessed (25). This was also the case with our protocol, where the intended sedation level was the minimum required to allow the procedure to be completed with full patient tolerance.

The risk of sedation-associated complications increases with depth, as the respiratory center becomes depressed and the risk of hypoxemia and cardiovascular complications rise, as defined by Hung et al. (26). In our study we demonstrated that excessive sedation may be significantly reduced, with a very low rate over the last year. Sedation-related complications during digestive endoscopic procedures are usually transient and mild. The risk of these complications increases when severe comorbidities are present. Hemodynamic complications are most common in digestive endoscopy (27), followed by respiratory adverse events. Although some authors consider hypoxemia the most common complication (28,29). In our study, hypertension and tachycardia were most common, possibly related to sedation level restrictions. The recording of complications was meticulous and software-automated. This allowed greatly improved recordings, as electronic complication recording systems represent a potentially effective tool for quality improvement (30).
Many studies define hypoxemia using a SaO2 level and a varying time that ranges from 20 sec (31) to 30 sec (32). We studied all respiratory events, including any decreases of SaO2 below 90%, provided the pulse oximetry curve remained stable without interferences, shortness of breath, airway opening maneuvers, etc. In our series, the rate of respiratory events was 1.07%. This incidence is similar to that reported by some other authors, with hypoxia rates of 0.7% in patients sedated with propofol administered by gastroenterologists (33) and much lower than that reported in many studies, which was up to 4.4% (34), 6.7% (35), or even 12.8% (36). The study by Uzman et al. (37) compared patients sedated with propofol versus patients sedated with midazolam and opiate, the reported hypoxemia rate was 14% in the propofol group and 4% in the benzodiazepine + opioid group.

The factors found were age, ASA, obesity and a history of chronic obstructive pulmonary disease, similar to the report by Long et al. (38). The hypotension rate in our study was 4.34% lower than that reported by Ma et al. (6.25%) (39). In the study by Khalid-de Bakker et al. (40) hypotension rate was 8.9% among patients undergoing screening for colorectal cancer. Tang et al reported a series with a hypotension incidence of 9.1%, with no association with antihypertensive medication (41).

The significance of endoscopy-related pain is due to the fact that it represents the most important obstacle in the procedure, which makes it the main item to avoid when a patient is sedated. The study by Ekkelenkamp et al. (2) administered slightly lower doses of midazolam and fentanyl compared to our study and reported that 7.7% of patients experienced discomfort during the procedure. In our opinion, inadequate sedation leading to test discontinuation represents a major pain marker during the procedure, with the incidence reaching up to 4.1%. We must also highlight that a small study by Kravochuck et al. (42) of interventional colonoscopy found that pain during the procedure was correlated with endoscopist technical expertise, rather than sedation level score. Thus, we feel that the mechanisms should be devised with anesthesiologists available to deepen sedation for patients that fail to tolerate with moderate sedation. We are currently developing a protocol to this end.

Unexpected hospitalization of outpatients after endoscopy is a key indicator for ambulatory major surgery, therefore this was included in our indicators group. Our study showed that
the overall rate of admissions was slightly lower than that reported by ourselves for ambulatory surgery (6) and that the most common causes of unscheduled admission were similar to those reported for patients undergoing ambulatory surgery. Satisfaction is a quality dimension that must be present in any patient-centered care process. Different studies focus on patient satisfaction degree by using non-comparable questionnaires. Uzman et al. (37) discussed the degree of patient satisfaction in a study that compared propofol and midazolam. This study reported higher satisfaction levels in those who received propofol versus those treated with midazolam plus opioid, in line with the results reported by Schroeder et al. (43). Cancellation of scheduled procedures has a negative impact on the patients involved (44). In our series, the failure of a patient to attend represented around 70% of cancelled scheduled procedures. In order to decrease this rate, one study recently reported (45) that sending reminder SMS in advance reduces the incidence of call-offs by 50%, from 8% in the control group (similar to our results) to 4.8% in the group receiving an SMS, \( p < 0.001 \).

The limitations in our study derive from the fact that it is a protocol specifically designed for our hospital, which renders extrapolation of results difficult. To conclude, multidisciplinary, patient-centered programs for sedation in the setting of digestive endoscopy guarantee patient safety with a high level of satisfaction. Ongoing monitoring over the entire process will allow the implementation of measures in order to improve medical procedures.

REFERENCES


Table 1. Overall demographics

<table>
<thead>
<tr>
<th>No. of patients</th>
<th>9530</th>
<th>Sex (M/F)</th>
<th>3695/5835</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>Median; IQR</td>
<td>Size</td>
<td>Median; IQR</td>
</tr>
<tr>
<td>Age</td>
<td>56.78; [22.7]</td>
<td>164; [12]</td>
<td></td>
</tr>
<tr>
<td>Weight</td>
<td>70; [18]</td>
<td>IMC</td>
<td>26.1; [5.97]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test type</th>
<th>No. (%)</th>
<th>Prior conditions</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colonoscopies</td>
<td>7122 (74.73%)</td>
<td>Cardiovascular</td>
<td>622 (6.52%)</td>
</tr>
<tr>
<td>Gastroscopies</td>
<td>1662 (17.44%)</td>
<td>Respiratory</td>
<td>759 (7.96%)</td>
</tr>
<tr>
<td>Both</td>
<td>685 (7.19%)</td>
<td>Dyslipidemia</td>
<td>2038 (21.39%)</td>
</tr>
<tr>
<td>Therapeutic</td>
<td></td>
<td>Blood hypertension</td>
<td></td>
</tr>
<tr>
<td>colonoscopy</td>
<td>53 (0.56%)</td>
<td></td>
<td>2118 (22.22%)</td>
</tr>
<tr>
<td>Therapeutic</td>
<td></td>
<td>Smoking</td>
<td>3147 (33.02%)</td>
</tr>
<tr>
<td>gastroscopy</td>
<td>5 (0.05%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ERCP</td>
<td>0 (0%)</td>
<td>Diabetes</td>
<td>695 (7.29%)</td>
</tr>
<tr>
<td>Echoendoscopy</td>
<td>3 (0.03%)</td>
<td>Obesity (BMI &gt; 30 kg/m²)</td>
<td>2079 (21.82%)</td>
</tr>
<tr>
<td>Inpatients</td>
<td>517 (5.42%)</td>
<td>ASA 1</td>
<td>2391 (25.09%)</td>
</tr>
<tr>
<td>Outpatients</td>
<td>9013 (94.58%)</td>
<td>ASA 2</td>
<td>5906 (61.97%)</td>
</tr>
<tr>
<td>Elective</td>
<td>9393 (98.56%)</td>
<td>ASA 3</td>
<td>1215 (12.75%)</td>
</tr>
<tr>
<td>Emergency</td>
<td>137 (1.44%)</td>
<td>ASA 4</td>
<td>18 (0.19%)</td>
</tr>
</tbody>
</table>

Table 2. Complications during digestive endoscopy (Gs group)

<table>
<thead>
<tr>
<th>Complications during endoscopy</th>
<th>Postoperative complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>No. of patients in PARU</td>
</tr>
<tr>
<td>-----------------</td>
<td>------------------------</td>
</tr>
<tr>
<td>Unexpected cardiorespiratory arrest</td>
<td>0 [0%]</td>
</tr>
<tr>
<td>Excessive sedation/Antagonist use</td>
<td>196 [2.06%]</td>
</tr>
<tr>
<td>Colon perforation</td>
<td>[0%]</td>
</tr>
<tr>
<td>Bleeding</td>
<td>2 [0.02%]</td>
</tr>
<tr>
<td>Pain</td>
<td>448 [4.7%]</td>
</tr>
<tr>
<td>Nausea</td>
<td>8 [0.08%]</td>
</tr>
<tr>
<td>Vomiting</td>
<td>3 [0.03%]</td>
</tr>
<tr>
<td>Respiratory events</td>
<td>102 [1.07%]</td>
</tr>
<tr>
<td>Anxiety</td>
<td>3 [0.03%]</td>
</tr>
<tr>
<td>Hypertension</td>
<td>1190 [12.49%]</td>
</tr>
<tr>
<td>Hypotension</td>
<td>414 [4.34%]</td>
</tr>
<tr>
<td>Bradycardia</td>
<td>485 [5.09%]</td>
</tr>
<tr>
<td>Tachycardia</td>
<td>1097 [11.51%]</td>
</tr>
</tbody>
</table>

Complications at home over the subsequent 24 hours

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>1190 [12.49%]</td>
<td>Survey respondents</td>
</tr>
<tr>
<td>Discomfort</td>
<td>1061 [28.1%]</td>
<td></td>
</tr>
<tr>
<td>Pain requiring painkillers</td>
<td>39 [1.03%]</td>
<td></td>
</tr>
<tr>
<td>Nausea/Vomiting</td>
<td>45 [1.19%]</td>
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</tr>
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</table>
Table 3. Factors that play a role in complication development (multivariate analysis)

<table>
<thead>
<tr>
<th>Factor</th>
<th>OR</th>
<th>95% CI</th>
<th>p-value</th>
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<tbody>
<tr>
<td><strong>Respiratory events</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>COPD</td>
<td>2.00</td>
<td>(1.26-3.18)</td>
<td>0.0033</td>
</tr>
<tr>
<td>ASA</td>
<td>1.65</td>
<td>(1.29-2.09)</td>
<td>0.0000</td>
</tr>
<tr>
<td>Obesity</td>
<td>1.56</td>
<td>(1.15-2.12)</td>
<td>0.0043</td>
</tr>
<tr>
<td>Age</td>
<td>1.02</td>
<td>(1.01-1.03)</td>
<td>0.0004</td>
</tr>
<tr>
<td><strong>Hypotension</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood hypertension</td>
<td>0.66</td>
<td>(0.51-0.86)</td>
<td>0.0022</td>
</tr>
<tr>
<td>Gastroscopy</td>
<td>0.20</td>
<td>(0.12-0.31)</td>
<td>0.0000</td>
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<td>Programmed</td>
<td>0.39</td>
<td>(0.23-0.66)</td>
<td>0.0005</td>
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<td><strong>Bradycardia</strong></td>
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<tr>
<td>Ischemic heart disease</td>
<td>2.22</td>
<td>(1.53-3.22)</td>
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<tr>
<td>Heart valve disease</td>
<td>2.29</td>
<td>(1.39-3.75)</td>
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<td>1.63</td>
<td>(1.38-1.93)</td>
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<td>(1.01-1.02)</td>
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<td>Anemia</td>
<td>0.55</td>
<td>(0.34-0.9)</td>
<td>0.0165</td>
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**Fig 1.** Presedation indicators. A. Percentage of righted informed consents. B. Patients sedated off-protocol by non-anesthesiologists. C. Safety checklist reviewed.

**Fig 2.** Indicators during the endoscopic procedure. A. Percentage of patients taken beyond the accepted sedation level. B. Cardiorespiratory complications associated with sedation. C. Percentage of patients with post-endoscopy pain.
Fig. 3. Postsedation indicators. A. Annual percentage of outpatients with an unexpected hospitalization. B. Satisfaction level of patients after survey at 24 hours. C. Percentage of procedures called off before initiation.