1130-0108/2017/109/8/602-604
Revista Española de Enfermedades Digestivas

Rev Esp Enferm Dig
2017, Vol. 109, N.º 8, pp. 602-604

Letters to the Editor

Propofol sedation implementation: utility of the failure mode and effect analysis. Patient focused quality and safety

Key words: Propofol sedation. Quality and safety. Failure mode and effect analysis.

DOI: 10.17235/reed.2017.4976/2017

Dear Editor,

Sedation is a key component of digestive endoscopy. While ensuring procedural safety and quality represents a primary goal, a detailed assessment of patient-focused risks and improvements is lacking on most occasions. The failure mode and effect analysis (FMEA) is a useful tool in this context as a means of raising barriers and defense mechanisms to prevent adverse events from happening.

We report the results obtained with FMEA in our unit with regard to propofol sedation implementation. We identified sedation and immediate recovery (Table 1) as the most sensitive stages. The whole process was monitored, and the established protocol monitored the process from completion of the examination and leaving the examination room to subsequent consciousness recovery (Aldrete ≥ 9) and vital sign normalization.

Forty-seven complications (3.6%) were recorded: 30 desaturation (63.8%), six hypotension (12.8%), five bradycardia (10.6%), two laryngospasm (4.3%), two adverse reaction, one tachycardia and one aspiration case in a total of 1,326 patients with a mean age of 57.81 ± 15.36 (14-92) years and low anesthetic risk (94.6% ASAI-II). They were managed with conventional support measures and did not require hospital admissions, being identified during the sedation and monitored recovery phases.

Discussion

Sedation safety during digestive endoscopy has always been a concern. Protocols and various consensus guidelines are available from major scientific societies (1,2). Before a protocol is applied, its usefulness and feasibility should be assessed. In this regard, the FMEA is helpful. This tool allows the identification, evaluation and design strategies to improve potential process-related failures by analyzing their effects, causes, severity and frequency. In addition, there is a possibility of timely detection (3).

Adrián Huergo-Fernández[1], Pedro Amor-Martín[1] and Fernando Fernández-Cadenas[2]

[1]Department of Digestive Diseases. Hospital Álvarez-Buylla. Mieres del Camino, Asturias. Spain. [2]Department of Digestive Diseases. Hospital Universitario Central de Asturias. Oviedo, Asturias. Spain

Table 1. FMEA during propofol deep sedation

Failure mode	*Effect*	*Causes*	*Detection method*	*Severity*	*Occurrence*	*Detection*	*RPI*	*Actions and recommendations*
Missing medical record	History unknown Allergies unknown	Computer failure Misunderstanding Work overload	Prior interview Record review at exam room Allergic reaction	5	2	1	10	Medical record activation Contact family Adequate time between exams
Misunderstood prescription	Incorrect drug o dose	Misunderstood verbal instructions	Adverse reaction Nursing records	6	1	2	12	Nurse-verified verbal instructions Electronic prescription
Drug error	Incorrect drug doses	Similar presentation Nearby storage Drug unchecked	Unexpected reaction or no response Container seen after dose	6	1	2	12	Deletion of similar presentations Separate storage, labeling, color codes Check before dose
Failed monitoring during sedation	Overdose Adverse effect	Failed monitoring or vital sign assessment Work overload or inadequate staff	Unexpected reactions Altered vital signs Monitor acoustic alarm	9	2	2	36	Review monitor and vital signs during sedation Adequate staff and examination time
Failed monitoring during recovery	Adverse effect	Failed monitoring or vital sign assessment Inadequate recovery room staffing Work overload	Monitor acoustic alarm Unexpected reaction Absent vital signs	10	2	2	40	Out of recovery room with Aldrete ≥ 9 Monitoring protocol and vital signs assessment after sedation Accompanying person in recovery room Workload reduction or increased staffing

Severity (1-10): 1 = "none or very low", 10 = "dangerously high or catastrophic". Occurrence (1-10): 1 = "remote or unlikely", 10 = "very high or almost inevitable". Detection (1-10): 1 = "almost certain", 10 = "absolute uncertainty". Risk prioritization index (RPI) = severity x occurrence x detection.

References

1. Dumonceau JM, Riphaus A, Schreiber F, et al. Non-anesthesiologist administration of propofol for gastrointestinal endoscopy: European Society of Gastrointestinal Endoscopy, European Society of Gastroenterology and Endoscopy Nurses and Associates Guideline - Updated June 2015. Endoscopy 2015;47:1175-89. DOI: 10.1055/s-0034-1393414
2. Igea F, Casellas JA, González-Huix F, et al. Sedación en endoscopia digestiva. Guía de práctica clínica de la Sociedad Española de Endoscopia Digestiva. Rev Esp Enferm Dig 2014;106:195-211.
3. DeRosier J, Stalhandske E, Bagian JP, et al. Using health care failure mode and effect analysis: The VA National Center for Patient Safety's prospective risk analysis system. Jt Comm J Qual Improv 2002;28:248-67. DOI: 10.1016/S1070-3241(02)28025-6