

CLINICAL PRACTICE, MONITORING, AND PATIENT SAFETY DURING PROCEDURAL SEDATION IN FIVE COUNTRIES

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INTRODUCTION

- Procedural sedation is commonly used during gastrointestinal endoscopy procedures but carries increased risk.
- Clinical practice and response to procedural sedation-related adverse events (AEs, World SIVA task force¹ definitions) are currently unknown across geographies.
- Knowledge of global clinical practice would inform comparability of study outcomes across different settings.

AIMS

- Assess procedural sedation practice across various countries (France, Germany, Italy, the UK and the USA) and medical practices.
- Quantify and compare interventions applied to reported AEs.

METHODS

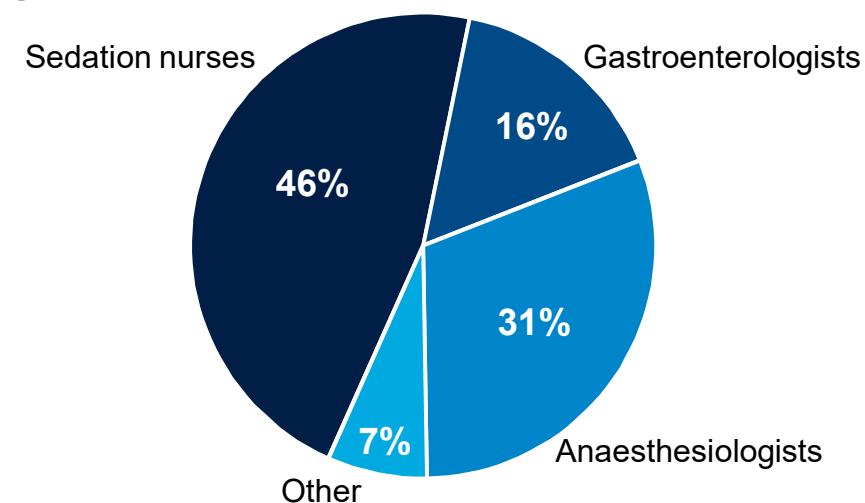
- Design and administer online survey (via 3rd party) to healthcare providers (at least 20 per country)
- Screen respondents to ensure only providers with sufficient procedural sedation experience and practice volume respond to questionnaire
- Process data in MS Excel and R to:
 - Analyze demographic and practice data (Chi-squared test)
 - Identify and replace outliers (Dixon Q-test) with global mean
 - Weight treatment pattern responses by respondent experience with the AE and how often the respondent provided outliers
 - Estimate overall treatment patterns by bootstrap replication and non-parametric inference testing

RESULTS (I)

Medical practice and sedation agents

- Providers were distributed across selected medical specialties (Figure 1)

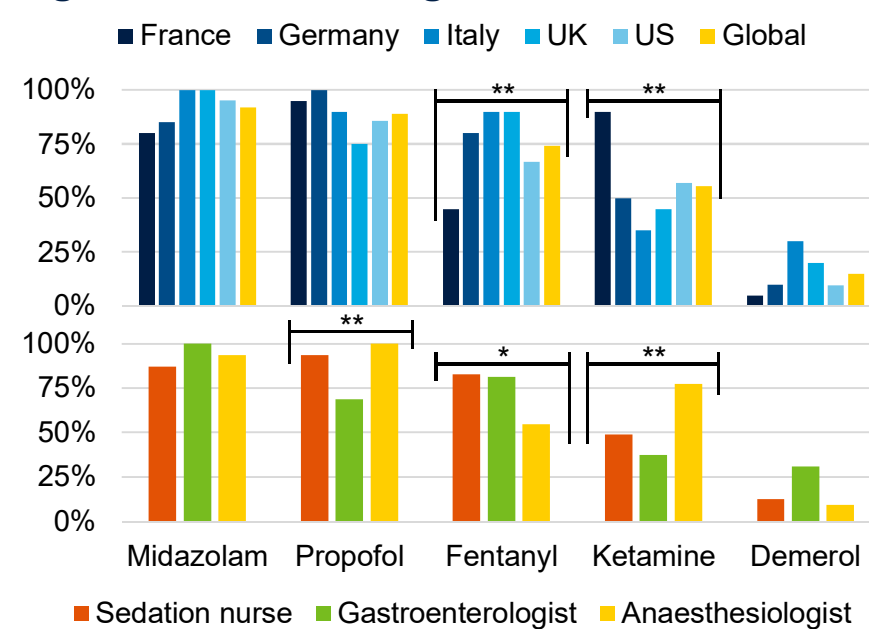
Figure 1: Respondent medical practices



Percentages of 101 respondents. "Other" includes cardiologists (3%), critical care specialists (3%) and plastic surgeons (1%)

- Use of sedation agents was similar by country and specialty, except for ketamine and fentanyl use (Figure 2)

Figure 2: Sedation agent use



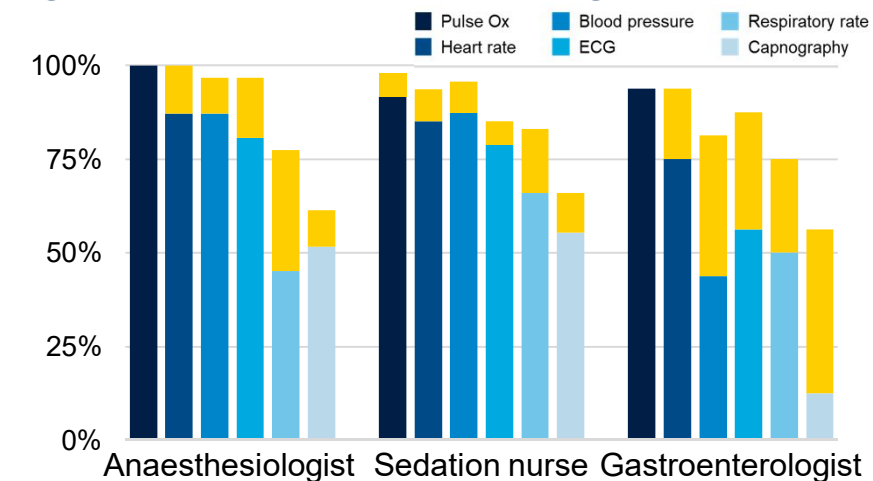
Percentages of respondents in corresponding category. Many respondents use more than one agent. Significance among respondents shown in each group: *p<0.05, **p<0.01

RESULTS (II)

Monitoring and adverse events

- Capnography use was most varied by country/medical practice (Figure 3)

Figure 3: Sedation monitoring practices



Bar height = respondents using the monitoring method; yellow = those who do not consider it standard of care.

- All SIVA-defined moderate and sentinel AEs were reported to have occurred
 - 2.0% reported seizure, 3.0% cardiac arrest in at least 1% of procedures in the last year
- Hypotension, brady- and tachycardia, and short, mild oxygen desaturation were the most common AEs (see abstract).
- AEs required interventions at differing rates; all could lead to delays (Table 1).

Table 1: Select adverse events and corresponding interventions

	None	Tactile Stimulation	Airway Repositioning	Supplemental Oxygen	Bag mask	Laryngeal mask	Call Anaesthesiologist	Procedure Delay
Hypotension	36.1% [27.9; 44.7]	5.0% [2.0; 10.0]	0.3% [0.0; 3.3]	18.2% [8.9; 28.7]	0.3% [0.0; 1.0]	0.4% [0.1; 1.0]	2.8% [0.9; 8.2]	4.0% [1.9; 7.2]
Bradycardia	57.7% [44.3; 67.8]	2.1% [0.8; 3.7]	0.7% [0.3; 1.7]	7.4% [4.2; 13.9]	3.1% [0.5; 6.6]	0.8% [0.2; 2.5]	3.2% [1.7; 5.3]	2.4% [1.3; 5.1]
Tachycardia	37.5% [23.7; 53.9]	0.1% [0.0; 0.7]	0.2% [0.0; 0.9]	21.7% [4.9; 47.6]	0.0% [0.0; 0.5]	0.0% [0.0; 0.4]	9.2% [3.1; 22.6]	2.1% [1.1; 3.5]
Oxygen desat. (mild, short)	20.8% [6.2; 35.5]	13.8% [7.0; 22.4]	9.4% [5.1; 42.2]	49.8% [30.6; 69.0]	12.0% [7.8; 20.3]	1.6% [0.4; 3.4]	8.4% [2.3; 14.9]	5.3% [2.6; 8.9]
Oxygen desat. (severe)	9.9% [3.5; 22.4]	26.7% [14.6; 40.7]	27.6% [12.2; 48.8]	80.8% [64.1; 92.4]	26.9% [18.5; 38.2]	7.9% [3.0; 21.6]	19.2% [8.0; 37.4]	19.1% [9.5; 27.4]
Apnea (long)	16.8% [7.3; 46.9]	37.7% [21.5; 53.6]	32.4% [18.2; 45.9]	47.9% [27.8; 64.2]	31.7% [18.1; 46.7]	11.7% [6.8; 19.3]	23.3% [13.3; 33.1]	6.5% [3.8; 12.5]

Values are median percentages of patients [interquartile range] expected to be treated with the above intervention for the given AE.

DISCUSSION

- Some differences were identified in sedation agents and monitoring methods.
- Monitoring methods used will influence the frequency of observation of some AEs.
 - Gastroenterologists demonstrated the greatest differential between monitoring used and its being considered standard of care.
 - Specialties agreed on the most common AEs.
- Treatment patterns were generally consistent
 - Oxygen desaturation demonstrated greater variability in treatment response.
 - Differences may in part be explained by breadth of SIVA definitions, or by the depth and duration of sedations performed by providers.

CONCLUSIONS

- Most treatment patterns are consistent across geography and practice.
- Gastroenterologists monitored respiratory parameters least often and reported the highest frequency of short, mild oxygen desaturation events.
- In regular practice, the most common AEs are relatively mild, but all can have an impact on patient flows in procedural delays.