Capnographic monitoring of midazolam and propofol sedation during ERCP: a randomized controlled study (EndoBreath Study).

This was to determine whether intervention based on additional capnographic monitoring reduces the incidence of hypoxemia during midazolam and propofol sedation for endoscopic retrograde cholangiopancreatography (ERCP). Patients (American Society of Anesthesiologists [ASA] I - IV) scheduled for ERCP under midazolam and propofol sedation were randomly assigned to a control arm with standard monitoring or an interventional arm with additional capnographic monitoring. In both arms detection of apnea prompted withholding of propofol administration, stimulation of the patient, insertion of a nasopharyngeal tube, or further measures. The primary study end point was incidence of hypoxemia (oxygen saturation [Sao 2] below 90 %); secondary end points included occurrences of severe hypoxemia (Sao 2 <= 85 %), bradycardia, and hypotension, and sedation quality (patient cooperation and satisfaction). 242 patients were enrolled at three German endoscopy centers. Intention-to-treat analysis revealed no significant reduction in hypoxemia incidence in the capnography arm compared with the standard arm (38.0 % vs. 44.4 %, P =
Apnea was more frequently detected in the capnography arm (64.5 % vs. 6.0 %, P< 0.001). There were no differences regarding rates of bradycardia and hypotension. Per-protocol analysis showed lower incidence of hypoxemia in the capnography arm compared with the standard arm (31.5 % vs. 44.8 %, P = 0.048). There was one death related to sedation in the standard arm. Sedation quality was similar in the two groups. Intention-to-treat analysis showed hypoxemia incidence was not significantly lower in the additional capnography arm compared with standard monitoring. Additional capnographic monitoring of ventilatory activity resulted in improved detection of apnea.

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