Original Article

Non-intubated general anesthesia in prone position for advanced biliopancreatic therapeutic endoscopy: A single tertiary referral center experience

ABSTRACT

Background and Study Aim: Advance biliopancreatic endoscopies are nowadays performed in non-operating room anesthesia (NORA) under general anesthesia (GA). We evaluate the outcomes of non-intubated patients in prone position who received GA for endoscopic ultrasound (EUS) and endoscopic retrograde cholangiopancreatography (ERCP) in a tertiary referral center for digestive endoscopy.

Patients and Methods: Anesthesiological records, anamnestic, and intraoperative data of patients who underwent advanced therapeutic biliopancreatic endoscopies at our tertiary referral center from January 2019 until January 2020 were collected in the present observational study.

Results: One hundred fifty-three patients (93 M; median age: 68-year-old; mean ASA status: 2) were considered eligible for a procedure in the prone position with GA in spontaneous breathing. Prone position was always the initial setting. Propofol administration through a target-controlled infusion (TCI) pump was the choice to achieve GA. In our experience, desaturation appears to be the most frequent adverse event, accounting for 35% of cases (55/153). Treatment foresaw additional oxygen through a nasopharyngeal catheter, which proved to be a sufficient measure in almost all patients (52/55). Other adverse events (i.e., inadequate sedative plan, pain, and bradycardia) accounted for 2.6% of cases (4/153).

Conclusions: Non-intubated GA in the prone position may be regarded as a safe procedure, as long as the anesthesiological criteria of exclusion are respected and the anesthesiological team has become acquainted with the peculiar NORA setting and familiar with the management of possible adverse events.

Key words: Deep sedation, ERCP, general anesthesia, prone position, therapeutic endoscopy

Introduction

Endoscopic ultrasound (EUS) and endoscopic retrograde cholangiopancreatography (ERCP), in their role of minimally invasive procedures with respect to surgical intervention, are often considered the main way to treat biliary and pancreatic

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diseases as well as many surgical complications, especially in patients unfit for surgery due to postoperative adverse events (i.e., septic shock). The time required and the increasing complexity of such maneuvers require avoiding unconscious movements.[1] General anesthesia (GA), as defined by the ASA statement,[2] can be considered the choice.[3,4] GA can be administered to a prone patient breathing spontaneously (as in our institution), with limited possibility to support ventilation due to shared airway. These procedures take place outside the operating room in a dedicated setting named non-operating room anesthesia (NORA), according to the principle to bring the place of care to the patient, which adds additional difficulty to the already complex anesthesiologist's task. In the present study, 158 patients submitted to advanced therapeutic biliopancreatic endoscopic procedures were analyzed with the purpose to report the advantages and adverse events of NORA in a tertiary referral endoscopy center.

Materials and Methods

This was a retrospective observational study.

We collected anamnestic and intraoperative data from anesthesiological records of patients who underwent advanced therapeutic biliopancreatic endoscopies at our center from January 2019 until January 2020. Resuming flowchart of the study is shown in Figure 1. All patients were evaluated by an expert anesthesiologist and if exclusion criteria were present, i.e., obesity, severe chronic obstructive pulmonary disease (COPD), obstructive sleep apnea syndrome (OSAS), pediatric patients, critical or mentally disturbed patients, or high risk of aspiration and periprocedural respiratory insufficiency, secured airways already in place (i.e., orotracheal intubation [OTI] or tracheostomy), the choice was GA with secured airways and supine position.[3,5–7] All patients involved in the present study signed an informed consent to participate. In patients eligible for the study, GA in spontaneously breathing patients in the prone position was performed. All patients independently reached prone position, thus avoiding possible nerve injury due to passive positioning, and had non-invasive monitoring based on clinical observation, continuous SpO_2, respiratory rate, and ECG monitoring, non-invasive blood pressure (NIBP) measured every 5 min. Capnography through Smart CapnoLine® Plus, although strongly recommended, was judged not reliable because of the frequent loss of signal detection due to the prone position and frequent dislodgement due to endoscopic maneuvers. In addition to this, capnography does not give any hint about the adequacy of ventilation.[8] We, therefore, decided to heighten surveillance, keep a steady eye on chest movements, and monitor respiratory sounds through a stethoscope. Spontaneous breathing was supported by oxygen 4–8 L/min through a double nasal cannula. GA was accomplished by dedicated anesthesiologists through intravenous (i.v.) drug administration, standard of care was sedation through the TCI pump infusion with propofol. TCI infusion range was between 2 and 5 gamma/mL (mean value: 3.15 gamma/kg) and was titrated according to the clinical evaluation of anesthesia level, following the American Society of Anesthesiologists (ASA) classification of the depth of anesthesia as well as the requested depth of anesthesia.

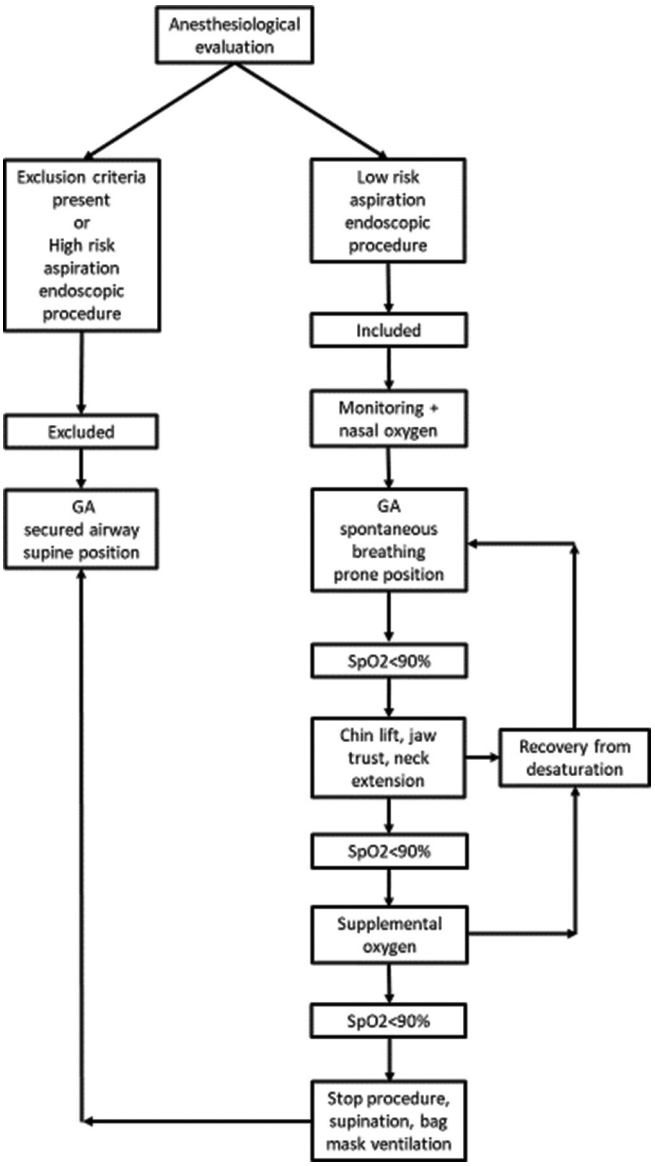

Figure 1: Flowchart of the anesthesiological plan followed in the present study

Low-dose pethidine (50–100 mg i.v.) was used as an analgesic agent if the procedure was considered painful as during pneumatic dilation or a large-bore self-expandable metal stenting.

Midazolam was administered only when the patient proved to be extremely anxious (average dosage: 0.07 mg/kg).

If SpO_2 fell under 90% for more than 30 s and first maneuvers (chin lift, jaw thrust, neck extension) remained ineffective, additional O_2 (4–8 L/min) was delivered through a nasopharyngeal catheter with its tip beyond the velopharyngeal seal. If rescue oxygenation proves ineffective, the procedure was stopped, and the patient was supinated and ventilated to restore normal oxygenation. The procedure had to be rescheduled with OTI [Figure 1]. Cardiovascular support was always guaranteed. To objectively define the difficulty of the biliopancreatic procedure, we used the "modified Shutz score" proposed by the American Society of Gastrointestinal Endoscopy. The scale comprehends three grades of difficulty: 1. Standard diagnostic and RX; 2. Billroth II diagnostic; stone >1 cm; intrahepatic duct stent; 3. Altered anatomy (Billroth II, Roux-en-Y, Whipple) therapeutic; pancreatic duct therapy; intrahepatic duct stones; lithotripsy; manometry.[9] Endoscopies were considered technically successful if all intended interventions were successfully completed during the procedure. Successful stone extraction required the complete clearance of the duct. Successful stenting required the insertion of a stent that traversed the pathology of interest/relieved duct obstruction.[8,10] We recorded the modifications of the strategy chosen at the beginning of the procedure by the anesthesiologist, the adverse events that forced any change in the strategy (desaturation, inadequate sedative plan, pain, bradycardia), and which maneuvers were necessary to resolve the problem. The expected and effective procedural time was also recorded as well as time to recovery and discharge.

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study was approved by the Bioethics Committee of Niguarda Hospital (No. 2021/076).

Statistics

Demographic, anthropometric, laboratory, and clinical data are expressed as median and interquartile ranges. Anamnestic data and classification of the procedure were indicated as the number of cases and percentage. Adverse events and rescue measures were expressed by the number and percentage of cases. Scheduled and procedural time, as well as awakening and recovery time, are expressed by median and interquartile range. Technical failure was recorded as the number and percentage of cases.

Results

A total of 158 cases (96 M; median age: 68; interquartile range [IQR]: 59–78); ASA status 1/2/3/4: 16/117/23/1) were analyzed during the study period. Five patients were excluded from the present study: three patients were already submitted to mechanical ventilation and two patients were intubated for the procedure because of aspiration risk not related to endoscopic procedures. One hundred fifty-three patients (93 M; median age: 68; IQR 59–78); were considered eligible for a procedure in the prone position with GA in spontaneous breathing. ASA status 2 patients accounted for 76% of cases. Patient characteristics are summarized in Table 1. Almost all patients (152/153, 99%) had a normal neurological status, 56% of the patients had a normal cardiovascular profile, and hypertension was the most frequent cardiovascular comorbidity (42%). Chronic obstructive pulmonary disease (COPD) and active smoking were present in 9% and 26% of patients. Also, 50% of patients had an altered gastroenteric or biliopancreatic anatomy due to previous surgery and included orthotopic liver transplantation (9/153, 6%). Prone position was always the initial setting. Propofol administration through a target-controlled infusion (TCI) pump (147/153, 96%) was the choice to achieve GA. The median target effect-site drug concentration (CET) value was 4 μg/mL (IQR: 3.5–4.5). In a percentage of cases, midazolam (3/153, 2%) and pethidine (18/153, 12%) were added to propofol administration. During the procedure, preoperative anesthesiological strategy was confirmed in 63% (97/153) of cases [Table 2]. In our experience, desaturation appeared to be the most frequent adverse event, accounting for 35% of cases (55/153). In 4% (2/55) of desaturation cases, simple measures such as chin lift, jaw thrust, and neck extension represented a valid rescue. Additional oxygen through the nasopharyngeal catheter with its tip beyond the velopalatine seal proved to be a sufficient measure in 52 of 55 cases. One of the patients (1/55) needed supination and bag-mask ventilation. Circulatory support using inotropes or vasoconstrictors was never needed in the present study; in one case, procedural inflation of air-induced bradycardia and atropine administration became necessary. According to endoscopic classification, 22 grade 1, 52 grade 2, and 79 grade 3 procedures were performed. Elective (143/153) and urgent (10/153) procedures were both included in the study. The mean preprocedural scheduled time was 30 min (IQR: 30–45); the real mean procedure time was 57 min (IQR: 30–69, 57 ± 37 min). Of all the procedures, 67% (102/153) required a combined EUS-ERCP approach. Technical failure was seen in 7% (11 grade 3 procedures).

Table 1: Study population data

	Median (IQR)	%(*n*=153)
Age (years)	68 (59-78)	
Male sex		61 (93)
Body mass index	24 (22-26)	
No neurological comorbidity		100 (152)
No cardiovascular comorbidity		51 (78)
Arterial hypertension		42 (64)
COPD		9 (13)
Active smoker		26 (40)
Patients from other hospitals		26 (39)
Previous OLTx		6 (9)
GE surgically altered anatomy		44 (74)
Creatinine (mg/dL)	0.9 (0.8-1.2)	
Hb (g/dL)	13.4 (12-14)	
INR	1.1 (1-1.2)	
aPTTr	1 (0.9-1.1)	
ASA		
1		10 (15)
2		76 (116)
3		14 (21)
4		0 (0)
STOP-BANG questionnaire >3		19 (29)
Starting prone position		
SpO_2		0 (0)
<90%		3 (4)
<94%		8 (12)
<97%		

BMI: Body mass index, COPD: Chronic obstructive pulmonary disease, OLTx: Orthotopic liver transplantation, GE: Gastroenteral, Hb: Haemoglobin, INR: International normalised ratio, ASA: American Society of Anesthesiologists, STOP-BANG: Snoring tiredness,observed apnea, blood pressure, body mass index, age, neck circumference and gender, SpO_2: Oxygen saturation

Discussion

The increasing development of endoscopic operative procedures, where the diagnostic aspect is deeply entwined with the therapeutic act, contributed to heightening the need for anesthesiological support outside the operating room (OR).[4] Our endoscopy unit is a national tertiary referral center with a high incidence of complex biliopancreatic endoscopies. Such procedures, which often represent the preferred way to treat heavily compromised patients, needed a deep level of unconsciousness to guarantee complete immobility. These tasks have been successfully performed under GA without OTI (failure rate: 7%). Many authors speak of sedation or deep sedation when the patient is breathing spontaneously and of GA when an endotracheal tube secures the airway; in our opinion, considering the depth of anesthesia necessary to perform advanced therapeutic endoscopies, we can eagerly talk of GA with spontaneous breathing and without endotracheal tube because it is the level of sedation itself that makes the difference between deep sedation and GA.[4,5,11] We consider GA being the only acceptable choice for the procedure according to the ASA definition,[2] because it realizes the necessary depth of anesthesia and keeps the patient motionless, thus permitting the precise and delicate endoscopic maneuvers. The challenge is to achieve a GA level in a spontaneously breathing prone patient where an endoscope *de facto* prevents manual ventilation, nevertheless realizing the optimal conditions for a safe upper GI procedure. The main challenge in this setting is to counteract the most common adverse event, i.e., respiratory failure, often due to over-sedation, according to Metzer[10] and Goudra.[5] They reported that the proportion of respiratory adverse events in NORA, according to the number of claims, was double compared to the incidence of similar events in OR (44 vs. 20%; $P = 0.001$).[5,10] Again, most of such respiratory events were due to desaturation following inadequate ventilation and oxygenation, which apparently have a seven times higher incidence in NORA than in OR (21% vs. 3%).[5,12] Goudra reported that up to 72% of adverse events (cardiac arrest) in endoscopic setting was related to airway management problems.[5,13] Our results showed that we faced the same problem even if we did not experience adverse cardiological events (desaturation rate: 35%). We decided to submit every patient to GA, whose depth had to be assessed continuously. It goes without saying that monitoring must adhere to the full standard prescribed by ASA,[14] including continuous electrocardiogram, non-invasive blood pressure check at given intervals (every 5 min), pulse oximetry, and capnography when feasible.[3,15,16] These measures, while going toward an acceptable degree of procedural safety, still miss the point. The main issue remains the difficult control of the airway. As a matter of fact, all upper gastrointestinal procedures do not allow to ventilate the patient until the endoscope is in place. Withdrawal is possible but the procedure must be interrupted,[8] and it will have to be repeated later on or started again. Routine OTI provides optimal control of the airway, according to the *primum non nocere* strategy, but requires time and is reserved for selected procedures.[1,12] Daily routine is supposed to be run with GA without OTI, partly because it has become a safe procedure (need for supination 1/153) if administered by skilled personnel and partly because of the elevated turnover, particularly if the activity takes place in tertiary referral centers. A consistent quote of experience in this setting becomes extremely valuable when there is a need to quickly evaluate a patient and decide if the patient can afford a GA with spontaneous breathing procedure or needs OTI.[1] The anesthesiologist must therefore heighten his skill in the management of the airway to counterbalance the absence of a secure airway, which remains the major concern.[8] The

Table 2: Anesthesiological planning

	Median (IQR)	%(*n*=153)
Maintenance of scheduled anesthesiological plan		63 (97)
Adverse event: desaturation		35 (55)
Adverse event: inadequate sedative plan		2 (3)
Adverse event: intraprocedural pain		1 (1)
Adverse event: Bradycardia		1 (1)
Changes in anesthesiological plan: supplemental O_2		35 (53)
Changes in anesthesiological plan: supination		1 (1)
Changes in anesthesiological plan: deepening of anesthesia		2 (3)
Changes in anesthesiological plan: adjunct of analgesic drug		1 (1)
Changes in anesthesiological plan: atropine		1 (1)
Awakening time (min)	5 (4-6)	
Recovery time (min)	16 (14-16)	

standard source of oxygen, i.e., nasal cannulae, could easily become inadequate. According to Goudra,[8] oxygen support through the nose may become impaired during deep sedation because the negative intraluminal pressure in the pharynx is not any more counterbalanced by the tone of the upper airway musculature, which in the awake patient avoids the closure of the upper airway. The collapse of the soft palate against the posterior pharyngeal wall (velopharyngeal block) *de facto* does not allow free airflow from the nose toward the trachea. In addition to this, a second obstruction mechanism due to retrolingual collapse impedes active lung ventilation. This double block may be overcome by nasopharyngeal or even nasopharyngeal tube, for instance, an 18 or 20 Fr silicone suction catheter. This simple device, if positioned beyond the velopharyngeal mechanism, allows a dramatic improvement in hypoxemia. Additional aid may be guaranteed by the presence of the endoscope, which may act as a stent of the airway, its bulk preventing the collapse of the tissue at the pharyngeal level, thus allowing oxygen to reach the trachea and lungs.[8] The prone position has been chosen for procedural as well as physiologic reasons. The prone position seems to heighten the technical success rate of ERCP with a slightly lower mean duration.[17] It helps minimize the airway collapse due to the velopharyngeal mechanism and the falling off the tongue, as already discussed. In addition to this, it is well known how gravity may influence both ventilation and perfusion.[18] Close surveillance of ventilation parameters may explain the lower incidence of respiratory adverse effects reported in our experience with respect to the literature.[5] This attitude could also explain, in part at least, that only one patient had to be bag-mask ventilated after emergency supination and interruption of the procedure.

In addition to this, respiratory failure has often been ascribed to drug overdosage.[12] Being aware of the narrow path between the need for adequate anesthesia level and the need of maintaining sufficient tissue oxygenation, we chose TCI with propofol, which was considered a safe way to administer GA avoiding overdosage.[5,12,19] The current opinion recommends the creation of a small pool of anesthesiologists dedicated to invasive endoscopic/radiologic procedures and familiar with the unusual location (NORA team). It has been demonstrated that regular anesthesiologists are more efficient than occasional colleagues[1,5,19] and may be helpful in terms of cost-saving and, much more than this, of patient safety. Measured values of mean oxygen saturation were higher when sedation or anesthesia was administered by a dedicated pool.[5] Procedures went smoother and wakening time was shorter, thus accomplishing the habit of quick turnover of patients typical of our setting. An adequate postoperative recovery room with experienced nurses permitted a safe stay within the NORA until the patient was ready to be dismissed.

The main limitations of this study are the monocentric design and bias related to a strict selection of patients undergoing non-intubated GA in the prone position, clinically mandatory to avoid major adverse events. Indeed, further prospective studies might confirm our results, also in terms of the selection of patients and the need for a dedicated NORA team.

According to Schumann,[11] we may adhere to his words: "sedation is a *continuum* of altered consciousness, ranging from moderate to deep sedation and general anesthesia." Our experience confirmed that advanced therapeutic biliopancreatic procedures need GA to be accomplished and that it is possible to achieve and maintain the GA level without OTI even in NORA. GA in a prone position may be regarded as a safe procedure, as long as the anesthesiology team has gained enough skills to successfully manage possible adverse effects in this peculiar setting, first of all, respiratory failure.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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