Prevalence of Anesthetic and Gastrointestinal Complications of Endoscopic Retrograde Cholangiopancreatography

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Abstract

Background: Endoscopic retrograde cholangiopancreatography (ERCP) is an endoscopic method for treatment of many biliary diseases. With respect to rapid recovery and more patient comfort, this procedure is currently performed under light general anesthesia (GA) or conscious sedation.

Objectives: The current study aimed to clarify that intravenous sedation or light general anesthesia can be performed without great fear of anesthesia related complications in ERCP patients and sedative doses of propofol can be used safely in outpatient settings under the supervision of an expert anesthesiologist.

Methods: This is a cross-sectional study on 1023 ERCP patients under light GA during 2014 - 2018 in Qom, Shahid Beheshti Hospital. Data were collected by a checklist and were analyzed by using chi-square test in SPSS V.22.

Results: From 1023 patients, 501 (48.97 %) were male and 522 (51.03 %) were female with a mean age of 47.2 ± 6.7 years. The most common finding in ERCP was choledocholithiasis (76.15 %). The most common complication was hemodynamic instability (37.01 %) followed by desaturation (11.65 %) both of them were anesthesia related. Prevalence of GI (gastrointestinal) related complications was 13.39 %. The most common GI related complications were pancreatitis (7.92 %) and bleeding (3.32 %). Total mortality rate was 0.88 %.

Conclusions: ERCP related complications are inevitable but can be controlled by early diagnosis and clinical experience. Severe complications and high risk patients may increase the mortality and morbidity of the procedure. Anesthesia related complications are more frequent than GI related unwanted events. Fortunately, the most common anesthesia related complications are readily manageable and are minor in nature when an expert anesthesiologist is present in the scene. Close monitoring of the patient’s vital signs should be the mainstay of the safe procedure.

Keywords: Anesthesia, Complication, ERCP, Endoscopy, Pancreatitis, Patient Comfort, Propofol, Remote Location Anesthesia

1. Background

Endoscopic retrograde cholangiopancreatography (ERCP) is a complex endoscopic procedure which can be used for diagnosis and treatment of biliary and pancreatic diseases. With regard to the introduction of less invasive methods, including magnetic resonance cholangiopancreatography (MRCP) and endoscopic ultrasonography (EUS) for diagnostic purposes, the use of ERCP as a diagnostic tool had been restricted within the past decade (1).

ERCP was introduced in the 1970s and from that time, it has seen great improvement in techniques and methods. Like any other invasive procedure, ERCP may lead to some complications, which can be categorized into general and specific complications (2, 3). General complications are the same as any other endoscopic intervention, including perforation due to endoscope passage, drug reactions and sedation or anesthesia related complications (3, 4). ERCP is almost always accompanied with anxiety, pain and discomfort. In this regard, sedation/anesthesia is inevitable in this procedure. There are a variety of sedative/anesthetic approaches to enhance patients’ safety and comfort alongside providing the endoscopists’ satisfaction (5-7). Propofol based deep sedation is one of the safest and the most efficacious anesthetic methods in many centers (8, 9). Administering a hypnotic medication such as...
propofol should be under direct supervision of an anesthesiologist who is expert enough in airway management. Lack of professional human resources has forced some of Iranian gastroenterologists to perform endoscopic procedures in sub-optimal situations such as wakefulness and under local anesthesia, without enough sedation necessary for patient comfort; because of fear of apnea and other unwanted events related to sedative/anesthetic medications.

ERCP-specific complications include: hemorrhage, perforation of duodenum, pancreatitis and sepsis (3).

2. Objectives

With respect to the growing application of ERCP, this study aims to evaluate outcomes and complications of the procedure in patients who underwent ERCP in Shahid Beheshti Hospital, Qom, Iran during 2014 - 2018. This is the first study on anesthetic complications of ERCP in Iran with a large number of cases focusing on the role of anesthesiologists in enhancing patient safety.

3. Methods

This cross-sectional study was performed by the Gastroenterology and Hepatology Disease Research Center and Department of Anesthesiology and Critical Care of Qom University of Medical Sciences on 1023 ERCP cases in Shahid Beheshti Hospital, a tertiary medical center in Qom, Iran during 2014 - 2018. Patients with ASA-PS (American Society of Anesthesiologists-Physical Status) III or more and those with a predicted difficult airway were excluded. Need for an anesthetic technique other than light propofol based general anesthesia was another exclusion criterion of this study. After placing the patient in prone position, premedication by midazolam (25 mcg/Kg), fentanyl (2 mcg/Kg) and hyoscine (20 mg by slow intravenous injection) was delivered for all patients. Induction of general anesthesia was performed by injecting 1 mg/Kg of propofol over 2 - 3 minutes to achieve a desirable level of anesthesia followed by 1 mg/Kg/h as a maintenance dose. Monitoring by pulse oximetry, a 3 lead ECG and automated NIBP (non-invasive blood pressure) was performed immediately prior to the procedure and up to 30 minutes after its termination. All patients received supplemental oxygen via nasal cannula (3 l/min) during the peri-procedural period. All of the procedures were done in a fully equipped endoscopy unit by senior endoscopists under direct supervision of anesthesiologists. In post-procedural period, all patients were monitored closely for anesthesia and ERCP related complications for at least 24 hours. A checklist was used to collect data including patients’ demographics, ERCP findings and complications. With the aim of evaluating anesthesia related complications, we focused on hemodynamic instability, dysrhythmias, desaturation, prolonged apnea, aspiration, PONV (post-operative nausea and vomiting), headache, delirium, aphasia, masseter spasm, MI (myocardial infarction) and death. In the current study, hemodynamic instability was defined as “30 % or more changes in pre-procedural blood pressure or mean arterial pressure less than 60 mmHg or 20 % or more changes in pulse rate from baseline recordings”; cardiac dysrhythmia was known as “any abnormal rhythm other than the patient’s preoperative one”; “values less than 90 % for SPO2” was the definition of hypoxia; and apnea was marked as an anesthesia related complication when it lasted longer than 30 seconds.

Informed written consent was taken from all participants prior to the admission.

Mean, standard deviation and frequency were used to describe data. Analysis performed by chi-square test in Statistical Package for the Social Sciences (SPSS) version 22 with a P value < 0.05 significance level.

Procedures were performed by 3 gastroenterologists, using an Olympus® cv-180 device, 2 anesthesiologists, administering anesthesia medications and 4 anesthesia nurses monitoring the patients during and after the procedure.

4. Results

From the 1023 patients, 501 (48.97 %) were male and 522 (51.03 %) were female with a mean age of 47.2 ± 6.7 years and mean body mass index (BMI) of 26.6 ± 5.8. The most common finding during ERCP was common bile duct (CBD) stone with a prevalence of 76.15 %. Other common findings were benign stenosis (4.50 %) and malignant stenosis (4.20 %) respectively. There were 3 rare cases of parasitic disease, 1 case of ascariasis in the bile ducts and 2 cases of fasciola hepatica. All findings are presented in Table 1. CBD stone was found more prevalent in women than men (416 cases versus 363 cases) which was not statistically significant according to the P value = 0.062. As shown in Table 1, none of the findings were different among male and female. Anesthesia related complications are depicted in Table 2. Hemodynamic instability was the most prevalent complication in this report (37.01 %) and aphasia, masseter spasm or MI were not reported in any patient. Total prevalence of GI related complications was 137 among 1023 procedures (13.39 %). The most common complication was post ERCP pancreatitis, with a prevalence of 7.92 %, followed by bleeding from the site of sphincterotomy, which was seen
in 3.23% of cases. Table 3 summarizes GI related complications of ERCP separated by gender. According to the table, pancreatitis was more common among females than males which was statistically significant with a P value = 0.014. The prevalence of other complications was not different among male and female. Nine deaths occurred, 1 due to perforation of duodenum, 2 because of severe pancreatitis, 2 following cardiac arrest, 1 due to cholangitis and 3 directly related to anesthesia. Anesthesia related complications weren’t evaluated regarding gender.

5. Discussion

ERCP is a complex endoscopic procedure and may accompany some complications which may be fatal in severe cases. ERCP related complications are defined as any unwanted events that lead to unplanned hospital stay or prolongation of planned hospital stay. Complications may occur within 30 days from the procedure and can be grouped according to the severity. Severe complications include any event which leads to ICU admission, surgical intervention, hospital stay for more than 10 days or death (10).

Choledocholithiasis was the most common finding among patients, followed by benign and malignant stenosis of the common bile duct. Nalankilli et al., by evaluating 487 therapeutic ERCPs during 2011 - 2015, revealed that the most common indication of ERCP was CBD stones, followed by biliary stricture (of any causes) and bile leak (11). The prevalence of findings was compatible with our study.

The prevalence of gastrointestinal (GI) related complications was 13.39% (137 among 1023 cases) in our study. The rate of adverse events was reported 5% - 10% in previous studies (12, 13). Pancreatitis, with a frequency of 81 cases (7.92%) was the most prevalent GI complication and was significantly higher among females. The majority of available studies, including the studies by Gromski and Fogel (14), Ishikawa-Kakiya et al. (15) and Wang et al. (16), have mentioned pancreatitis as the most common ERCP related complication. Its higher prevalence among females was not surprising, as female sex is a known risk factor for post-ERCP pancreatitis (PEP) (17). Other patient related risk factors for PEP include young age (<50), past history of pancreatitis and sphincter of Oddi dysfunction (SOD). Injury from the instrument and contrast injection and difficult cannulation are procedure-related risk factors for pancreatitis. And finally, adequate training and experience of the operator, will decrease the risk of all GI related complications, including PEP (17, 18).

Bleeding from the site of sphincterotomy was the second common GI related complication with a total prevalence of 3.23% and was mild in most cases. It is important to avoid sphincterotomy in patients with a platelet count less than 50,000/µL or INR > 1.5, to prevent severe bleeding.

Total procedure related mortality rate in this study was 0.88% which has been reported to be about 2% - 3% in previous studies (19, 20).

From the window of anesthesia related complications, hemodynamic instability was the most common complication. As an incidental finding, we observed elevation of blood pressure in spite of intravenous injection of propofol in a significant proportion of patients that encouraged us to do another study regarding blood pressure changes in this group of patients in the near future. Hypotension is a common and well known complication of propofol injection as an anesthesia induction agent (21). Bradycardia was another unwanted event in our study that can be attributable to propofol or opioid injection. This recent feature of hemodynamic instability will be more prevalent when both the responsible drugs are used simultaneously (22). Desaturation was the second most prevalent anesthesia related complication in our study (11.65%) that is similar to the Cote et al. study (23). Maybe in some centers, general anesthesia with endotracheal intubation is the method of choice for anesthesia management of ERCP patients. Need for patient cooperation is the main reason for us to do this procedure while the patient is in conscious sedation state. Some authors recommend adding ketamine to the patient’s anesthesia regimen with the aim to prevent respiratory depression (22). In our study, for any case with continued desaturation we planned to do airway opening maneuvers such as chin lift, use of modified face mask ventilation, or nasal airway to prevent further decrease in oxygen saturation. Dysrhythmia was the 3rd most common anesthesia related complication in our study. However, it didn’t need any intervention at all. The reason for higher prevalence of arrhythmia in our patients compared to other studies such as Smith et al.’s (24) isn’t clear and it’s explanation needs further investigation. Aspiration following loss of consciousness is a common finding in patient without a secure airway. This is the main reason for advocating patients to fast for at least 8 hours prior to elective procedures requiring anesthesia. In prone position, maybe increased intraabdominal pressure can lead to regurgitation and aspiration of gastric contents. Assurance about the patient’s NPO time and proper padding in prone position may lead to lessening the risk of this unwanted event. In our study despite evident aspiration in 7 cases, aspiration pneumonia fortunately occurred in only 2 patients, but unfortunately one of them died in spite of intravenous antibiotic therapy and longer hospital stay to have a better respiratory care. Aspiration pneumonia is not a common event at all in other studies too and in this regard, general anesthesia with endotracheal intubation...
Table 1. ERCP Findings

| ERCP Finding                   | Total, No. (%) | Male, No. (%) | Female, No. (%) | P Value |
|--------------------------------|----------------|---------------|-----------------|---------|
| Choledocholithiasis            | 779 (76.15)    | 363 (46.60)   | 416 (53.40)     | 0.062   |
| Benign stenosis                | 46 (4.50)      | 26 (56.52)    | 20 (43.48)      | 0.461   |
| Malignant stenosis             | 43 (4.20)      | 27 (62.79)    | 16 (37.21)      | 0.127   |
| Ampullary malignant tumor      | 31 (3.03)      | 21 (67.74)    | 10 (32.26)      | 0.072   |
| Ampullary adenoma              | 14 (1.37)      | 9 (64.29)     | 5 (35.71)       | 0.423   |
| Pancreatic malignancies        | 21 (2.04)      | 14 (66.67)    | 7 (33.33)       | 0.190   |
| Biliary sludge                | 25 (2.44)      | 9 (36.00)     | 16 (64.00)      | 0.230   |
| Bile leak due to surgery       | 32 (3.13)      | 18 (56.25)    | 14 (43.75)      | 0.596   |
| Sphincter of Oddi dysfunction  | 23 (2.25)      | 9 (39.13)     | 14 (60.87)      | 0.404   |
| Echinococcal disease           | 6 (0.59)       | 4 (66.67)     | 2 (33.33)       | 0.683   |
| Biliary ascariasis             | 1 (0.10)       | 0 (0)         | 1 (100)         | -       |
| Fasciola hepatica              | 2 (0.20)       | 1 (50.00)     | 1 (50.00)       | 0.999   |
| Total                          | 1023           | 501           | 522             | 0.532   |

Table 2. Anesthesia Related Complications of ERCP

| Anesthesia Related Complications | Hemodynamic Instability | Dysrhythmias | Desaturation | Prolonged Apnea | Aspiration | PONV | Headache | Delirium | Death |
|----------------------------------|-------------------------|--------------|--------------|-----------------|------------|------|----------|----------|-------|
| Male, No. (%)                    | 363 (35.48)             | 64 (6.26)    | 165 (16.33)  | 5 (0.49)        | 4 (0.39)   | 5 (0.49) | 4 (0.39) | 1 (0.10) |       |
| Female, No. (%)                  | 393 (38.42)             | 53 (5.18)    | 77 (7.52)    | 5 (0.49)        | 8 (0.78)   | 9 (0.88) | 5 (0.49) | 1 (0.10) | 2 (0.19) |

Table 3. Gastrointestinal Related Complications of ERCP

| GI Related Complications         | Total, No. (%) | Male, No. (%) | Female, No. (%) | P Value |
|----------------------------------|----------------|---------------|-----------------|---------|
| Pancreatitis                     | 81 (7.92)      | 29 (35.80)    | 52 (64.20)      | 0.044   |
| Perforation of duodenum          | 3 (0.29)       | 2 (66.67)     | 1 (33.33)       | 0.990   |
| Perforation of common bile duct  | 1 (0.10)       | 0 (0)         | 1 (100)         | -       |
| Cholangitis                      | 9 (0.88)       | 4 (44.44)     | 5 (55.56)       | 1.000   |
| Abdominal abscess                | 2 (0.19)       | 1 (50)        | 1 (50)          | 0.990   |
| Abdominal hematoma               | 1 (0.10)       | 0 (0)         | 1 (100)         | -       |
| Hemorrhage from the site of sphincterotomy (Mild) | 24 (2.35) | 12 (50.00) | 12 (50.00) | 0.838   |
| Hemorrhage from the site of sphincterotomy (Moderate) | 7 (0.68) | 2 (28.57) | 5 (71.43) | 0.900   |
| Hemorrhage from the site of sphincterotomy (Severe) | 3 (0.29) | 1 (33.33) | 2 (66.67) | 0.990   |
| Death                            | 6 (0.59)       | 4 (66.67)     | 2 (33.33)       | 0.683   |

wouldn’t be strictly recommended (25). PONV is a common complaint of post-anesthesia care unit patients and opioids are in the top of the list of guilty medications responsible for that (26). Propofol with its antiemetic properties can play a prominent role in preventing this complication (26, 27). Fortunately, PONV was not a common complication in our patients as in others’ studies (25). Headache isn’t a common event in ERCP patients, but it can occur as a side effect of intravenous nitroglycerine injection with the aim of preventing post ERCP pancreatitis (28). In this study we didn’t use nitroglycerin for any reason, so we should look for another explanation for an occurring headache. Delirium in old publications was a known complication of ERCP due to the use of some potent benzodiazepines such as diazepam (29). Today, it’s not a worrying complication of ERCP and proper approach can prevent the occurrence and treat existing cases of it (30). Three anesthesia related mortality cases of our study happened due to fa-
tional dysrhythmia, aspiration pneumonia and prolonged apnea. We didn’t find any other uncommon complication of propofol based anesthesia (9).

5.1. Conclusions
Complications are a constant companion of any interventional procedure. Gastrointestinal related complications in endoscopic procedures such as ERCP are mainly operator related and in some cases are really unpredictable. Need for sedation/anesthesia for uncomfortable and painful procedures such as ERCP is inevitable too. Anesthesia related complications are more frequent than GI related ones in ERCP. It’s prudent to avoid such a risky procedure when indications are not strong enough. In other words, avoiding anesthesia is the best way to escape its complications. But when the procedure becomes necessary, there is no choice but safe anesthesia. Fortunately, the most common anesthesia related complications are readily manageable and are minor in nature when an expert anesthesiologist is present in the scene. Presence of an expert anesthesiologist and close monitoring of the patient’s vital signs should be the mainstay of the safe procedure. Adequate training and clinical experience in all team members plays an important role in preventing undesirable events.

Footnotes

Authors’ Contribution: Reza Aminnejad and Ahmad Hormati. conceived the presented idea. Reza Aminnejad developed the theory and performed the computations. Mohammad Saeidi developed the theoretical formalism, performed the analytic calculations and performed the numerical simulations. Abolfazl Mohamadbeigi verified the analytical methods. Mohammad Reza Ghadir supervised the project. Reza Aminnejad wrote the primary manuscript. Hamed Shafiee edited the primary version of the manuscript. All authors discussed the results and contributed to the final version of the manuscript.

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