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Sedation with Ketofol for Endoscopic Retrograde Cholangiopancreatography: High Flow Nasal Oxygen Versus Endotracheal Intubation with Controlled Ventilation

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ABSTRACT
Endoscopic retrograde cholangiopancreatography (ERCP) is used for diagnosis and treatment of biliary and pancreatic disorders both. With increased instrumentation and prolongation of the procedure, patient safety and comfort becomes of paramount importance. It has got anaesthetic implications also. In addition to safety, cost and gastroenterologist's satisfaction, haemodynamic and respiratory stability, recovery room stay and early discharge is important. Comparative study was carried out in two groups with Target Control Infusion (TCI) in patients with age above eighteen years with American Society of Anaesthesiologists (ASA) physical status grade I/II. The two groups comprised of high flow nasal oxygen (HFNO) with spontaneous breathing (n-25) in group A and endotracheal intubation and controlled ventilation (n-25) in group B respectively. Student's t-test was run to carry out test of null hypothesis as the mean of the populations from which the two samples were taken with less variance. Haemodynamic parameters were not found statistically significant (p-0.216). No significant difference was noted in recovery time. When airway was protected, better patient compliance was observed. Gastroenterologist's satisfaction was better in group B compared to group A, although statistically not significant (0.308).

INTRODUCTION

ERCP is important in the diagnosis and treatment of pancreatic and biliary diseases. This technique is gaining popularity in developing nations too, as being less invasive and reduces the requirement of open surgeries for pancreatic and common bile duct stones[1-3]. It has become very handy in the treatment of biliary injuries and stenting of bile ducts in cholangiocarcinomas. With the advent of newer muscle relaxants, induction agents, opioids and with significant development in last decade in sedation and anaesthesia, the process is being tailored to meet requirement of specific subgroups resulting in a sub speciality. Sedation for GI endoscopy evolved in the last decade which saw significant development in this area which unwrapped opportunities and challenges[4-6].

The depth of sedation during procedures is almost similar to general anaesthesia. However, unprotected airway remains a matter of concern. Propofol being a popular agent that is used has narrow therapeutic window translating from mild sedation to deep general anaesthesia rapidly. Patients with significant co morbidities are presenting on regular basis for ERCP. So with the advent of technology, length and complexity of procedures requiring increase in depth of sedation, maintaining patency of upper airway is a challenge. Preserving spontaneous ventilation, suppressing cough reflex is important for upper GI endoscopy and colonoscopy. Frequencies of cardiac arrest are reported to be high in upper GI endoscopy. Aspiration of gastric content seems to be the most important sedation related complication[7-9].

Sedation is used mostly for the procedure. However, it carries some risks like aspiration and apnoea. The use of sedation with airway protection may be necessary in some patients. Because of the co-morbidities in patients undergoing ERCP the optimization of the technique is necessary. We thus conducted a prospective study to compare two anaesthetic protocols i.e. High flow nasal oxygen (HFNO) with spontaneous breathing versus assisted ventilation. Patients in both the protocols were maintained on Target control infusion (TCI).

MATERIALS AND METHODS

After taking the approval from Institute Ethical Committee, patients scheduled for elective ERCP were taken up for study. Written informed consent was taken after necessary pre anaesthetic evaluation. All the 60 patients above 18 years were taken up for study as per inclusion criteria. An inclusion criterion was American Society of Anaesthesiologists (ASA) physical status I/II and overnight fasting. Exclusion criteria was age less than 18 years, allergy to contrast, drugs, full stomach, pregnancy, difficult intubation, seizure disorders and increased intracranial tension. All ERCPs were conducted by same team of anaesthesiologist and gastroenterologist.

Patients were kept fasting over night for eight hours and tab diazepam 5 mg was given as anxiolytic the night before the procedure. Next morning they were taken to the operating room. Basal heart rate, blood pressure, oxygen saturation and ECG were recorded. Proper vascular excess was secured by 16G/18G cannula via peripheral line and Ringer's lactate was infused.

Paracetamol infusion was given for subsequent analgesia. Pre oxygenation was done with 100% oxygen for three minutes. In group, A premedication was given with injection midazolam 2 mg intravenous (IV). Patients were induced to sleep with Injection propofol 2 mg kg^{-1} Body weight IV. Any apnoea was managed by bag and mask ventilation. Maintenance was performed with propofol and ketamine combination ketofol (2:1 ratio) by TCI infuser and high flow oxygen 8 L^{-1} min was given by nasal cannula to Group A spontaneously breathing patients. In group B, premedication with Injection midazolam 2 mg IV was given and induced to sleep with injection propofol 2 mg kg^{-1} BW. Intubation was done following injection succynylcholine 1.5 mg kg^{-1} IV. Maintenance was performed with propofol and ketamine combination ketofol (2:1 ratio) by TCI infuser. Ketofol in both the groups was maintained at a target plasma level of sedation. Muscle relaxant atracurium 10 mg IV was given intermittently to prevent movement of patient. Continuous monitoring of ETCO2, SpO2 and NIBP, ECG and heart rate were performed. Before starting the ERCP, patients were assessed for their level of sedation using the Modified Observer's Alertness/Sedation (MOAA/S) scale yielding at a score <2.

The primary end point of study was haemodynamic and respiratory parameters, cardiovascular complications, sudden apnoea and movement. In Group-A after the end of procedure the target concentration was set to zero. Recovery was observed following weaning of sedation and return of adequate breathing and response. In Group-B, it was end of intervention and extubation and weaning effect of sedation and muscle relaxant. Overall satisfaction of gastroenterologist was also recorded. Blood pressure, heart rate and mean arterial pressure (MAP) and oxygen saturation were recorded just before induction and continuously monitored. At the end of the procedure target concentration was set to zero[10,11]. Haemodynamic variations like heart rate and MAP was defined by variation over 30% as compared to reference values. Desaturation was defined as SpO2 less than 95%. Hypertension was treated by increasing

the depth of sedation by giving propofol bolus 20 mg IV. Hypotension was treated by increasing saline infusion or sparing dose of injection mephenteramine 6 mg IV. Overall satisfaction of gastroenterologist was graded as low (1), medium (2) and high (3). Patient recovery was observed in both the groups with the return of adequate spontaneous breathing with arousability. The patient was taken to post anaesthesia care unit (PACU), where the patient received oxygen by face mask. Discharge was done on the basis of score by MOAA/S>2.

All the 60 patients including exclusion criteria, keeping exclusion criteria n = 10 exclusion due to pregnancy-2, full stomach-2, age <18 years-4 and difficult intubation-2. 50 were selected for study. Allotted in two groups for comparative study of 25 in each group by toss method (Flow diagram Fig. 1). Distribution of cases for ERCP as mentioned in (fig. 2). Paired samples t-test was run to carry out test of null hypothesis as the means of the populations from which the two samples taken were equal with less variance. p-value is determined using table of values from t-distribution. $p<0.05$ was considered statistically significant.

RESULTS

A total of 50 patients were taken into study. No significant differences were noted between the two groups regarding age (p-0.308), sex (p-0.308), weight (p 0.308), BMI (p-0.308) and ASA classification (p-0.5) as shown in Table 1. Three cases were reported to have hypertension and tachycardia in group A and group B respectively (p-0.216) which got controlled after deepening the sedation and found not statistically significant. Two incidences of hypotension were observed in both the groups (p-0.249) which was managed by fluid infusion and found not statistically significant. Sudden apnoea was recorded in group A (p-0.159) not in group B as airway was protected by intubation. Sudden apnoea was managed by stopping the ERCP procedure and adjusting the nasal cannula. There was no precipitous fall in saturation. It was a brief episode and patient regained saturation. Patient was continuously observed for chest movement. ETCO2 was continuously monitored. There was no significant difference noted in recovery time (p-0.308) as noted in Table 2. Recovery in both the groups was matching as titrated dose of atracurium was given in group B, not full dose so that paralysis was not prolonged. Modified Alertness/Sedation Observers Scale (MOAA/S) criteria was used for recovery. Satisfaction level of gastroenterologist was assessed by numerical figure 1, 2 and 3 as low, medium and high respectively noted in Table 3 and Fig 3 was better in group B, though statistically not significant (p-0.308). No patient had any complications associated with drugs and had an uneventful recovery.

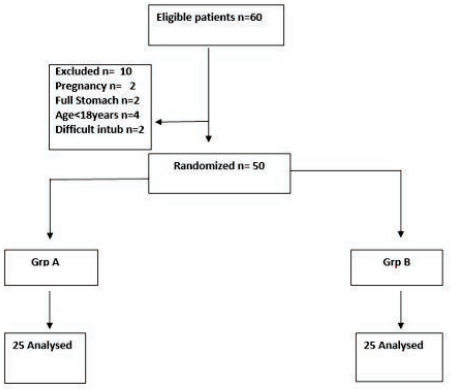

Fig. 1: Flow diagram of the process of study evaluation

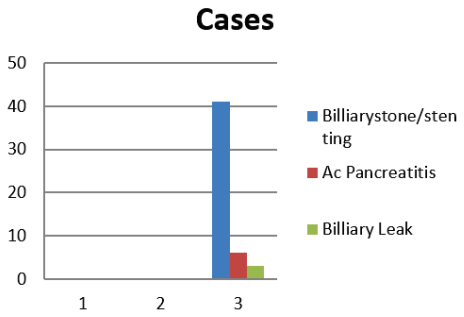

Fig. 2: Description of cases

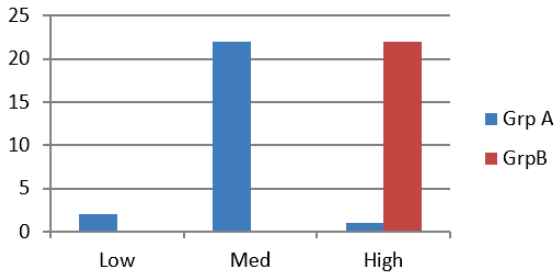

Fig. 3: Endoscopist's satisfaction

DISCUSSIONS

The ERCP technique is very often directed to a group of fragile population and so the spectrum of therapeutic application is going to expand. Anaesthesia and analgesia are important elements for endoscopic procedures. They reduce discomfort and stress to patients and so decrease morbidity. The anaesthetic technique used predominantly worldwide is deep sedation and general anaesthesia is reserved for difficult cases. Chainaki *et al*.[11] who studied ERCP stated that it is often a time consuming procedure which requires patient's cooperation and general anaesthesia should be considered in patients who are difficult to sedate. Propofol based techniques along

Table1: Demographic data

Characteristic	Group A (n = 25)		Group B (n = 25)		p-value
Age(years)	41.88±13.21		47.4±18.61		0.308
Sex	Male	Female	Male	Female	0.308
	05	20	09	16	
Weight(Kg)	59.84±9.27		57.52±9.0		0.308
Height(Cm)	157.72±7.62		156.7 (7.58)		0.308
BMI (Kg cm^{-2})	27.16±2.09)		25.67±2.45)		0.308
ASA status	I	II	I	II	
	20	05	20	05	0.5

Table2: Complications

Characteristic	Group A	Group B	p-value
Hypertension episode	03/22	01/24	0.216
Tachycardia	03/22	01/24	0.216
Hypotension episode	02/23	02/23	0.249
Arrhythmias	00	00	
Sudden apnoea	03/22	00	0.159
Desaturation	00	00	
Recovery time (min)	4.70±1.30	4.3+1.28	0.308

Table3: Endoscopist's satisfaction

Endoscopic satisfaction	Group A	Group B	p-value
Low	02	00	0.3085
Medium	22	03	
High	01	22	

with other adjunct drugs e.g. ketamine, remifentanyl and fentanyl are predominantly used in ERCP. In our study we used propofol along with ketamine (ketofol) in the ratio of 2:1, given at the rate of 2.5 mL kg^{-1} hrs by TCI infuser. Deep sedation reduces procedure time, improves the level of comfort, intra operative amnesia and prevents intra operative complications like gagging, aspiration and duodenal perforation. However, the deep sedation may compromise the safety of patient rendering them vulnerable to respiratory complications. Raksakietisak M reported aspiration pneumonitis, choking, regurgitation, desaturation and hypoxemia with high flow nasal supplimentation[12]. Causes of fall in saturation was mainly observed in advanced age due to decreased cardiopulmonary reserve, procedure duration and patient positioning. Basavana Goudra *et al*.[13] reported that hypoxic events were significantly reduced in morbidly obese patients by using nasal trumpet and connecting to Maplesion circuit and giving oxygen through it. Perioperative mortality from arrhythmias, myocardial infarction and cardiac arrest was also reported. The primary goal of the study was to assess the better technique of anaesthesia by TCI in group A with HFNO and in another group B where airway was protected by endotracheal tube. Study at our institution showed better patient compliance and comfort and less chances of apnoea in group B. Arguments for sedation are low cost, short duration interventions and no residual neuromuscular blockade. In our study we used titrated dose of atracurium which prevented gagging and breath holding with insignificant effect on recovery time which is similar to group A (HFNO).

CONCLUSION

From the observations it is concluded that there were no significant differences between two techniques as far as haemodynamic stability was concerned. When airway was protected, better patient compliance with no apnoea and higher gastroenterologist's satisfaction was observed.

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