

Safety of Conscious Sedation in Patients Undergoing Endoscopic Retrograde Cholangio Pancreatography

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ABSTRACT

Objective: To assess the safety of conscious sedation in patients undergoing endoscopic retrograde cholangio pancreatography (ERCP).

Study Design: An observational study.

Place and Duration of Study: Department of Gastroenterology, Liaquat National Hospital, Karachi, from April 2010 to April 2015.

Methodology: All patients underwent ERCP procedure under midazolam and/or nalbuphine were included. Safety was assessed by monitoring the hemodynamics and complications during procedure till discharge from hospital. SPSS version 20 was used for descriptive analysis.

Results: A total of 550 procedures were enrolled for the study. The mean age of the patients was 50.85 ±15.66 years. There were 197 (35.8%) males. Out of 550 procedures, only 2 (0.4%) reported complications. The study reports a success rate of 531 (96.5%) procedures who underwent ERCP with conscious sedation. Only 19 (3.5%) cases could not be completed successfully under conscious sedation and were converted to general anaesthesia.

Conclusion: The present study shows that ERCP technique is safe under conscious sedation as it delivers balanced tranquillity.

Key Words: Conscious sedation, General anaesthesia, Endoscopic retrograde cholangiopancreatography, Biliary disease.

INTRODUCTION

Endoscopic retrograde cholangio pancreatography (ERCP) is a challenging and lifesaving procedure to treat hepatopancreaticobiliary disorders. The pain and discomfort from the procedure may occasionally cause vigorous body motion, preventing safe examination.¹ One significant factor to counter pain and discomfort is the use of intravenous sedation.² Sedation is a technique by which depression of consciousness is achieved to alleviate the pain and discomfort associated with therapeutic procedures.³ One of the key factors determining the success of the procedure is the administration of either moderate or deep sedation.⁴ Currently, sedation is mainly performed using a benzodiazepine such as midazolam and a semi synthetic opioid like, nalbuphine hydrochloride; these have been adopted to alleviate the pain experienced during ERCP. Therefore, the use of sedative agent to a patient remains a topic of debate. Many studies favour usage of conscious sedation, while other studies suggest that since propofol has rapid onset and off-set

of sedation with quick recovery time, it should be preferred. According to a recommendation from American Society of Gastrointestinal Endoscopy (ASGE), deep sedation should only be preferred if the procedure is complex and time consuming.⁵ European Society of Gastrointestinal Endoscopy (ESGE) has published guidelines to provide general physicians with a comprehensive framework for propofol sedation during digestive tract endoscopy, including ERCP.⁶

Many gastroenterologist and anesthesiologists suggested that patients with less severe pathologies should be given conscious sedation that can be administered by the trained staff or by the physician himself to reduce cost of anesthesiologist-administered sedation.⁷ Many studies have also recommended propofol, administered by nurses or a gastroenterologist, as a safe and effective method to reduce the cost of anesthesiologist-administered sedation.⁸⁻¹⁰ Endoscopy units should assure to practise guidelines regarding procedure-related sedation, including certification, training of staff, maintenance of rescue equipment, formation of suitable emergency protocols, and quality assurance programme.³

There is not much local data available to assess the safety of conscious sedation during ERCP procedure. Hence, the objective of this study was to determine the safety and success rate of ERCP under conscious sedation.

METHODOLOGY

This was an observational study, conducted from April 2010 to April 2015, in the Department of Gastroenterology, Liaquat National Hospital, Karachi, after approval of

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Hospital Ethics Committee. Informed consent for ERCP under conscious sedation was taken. The inclusion criteria were all patients who underwent ERCP under influence of conscious sedation including weight-based midazolam and/or nalbuphine. Patients with severe cardio respiratory compromise (ASA IV and V) were excluded and not included in analyses as these patients require general anaesthesia.

Data were collected from patients' medical records retrospectively. The baseline demographics of each patient was recorded. Safety was assessed by monitoring the sedation related hemodynamics.

SPSS version 20.0 IBM, Chicago, USA, was used for data entry and analysis. Mean and standard deviation were calculated for quantitative variables. Frequencies

and percentages were calculated for qualitative variables like gender, presence or absence of obstructive jaundice, diagnosis.

RESULTS

During the study, a total of 550 patients underwent ERCP procedure, performed to either diagnose or treat hepatopancreaticobiliary disorders. The mean age of patients was found to be 50.85 ± 15.66 years. There were 197 (35.8%) male patients. Baseline demographics, presenting complaints and indication of ERCP, are outlined in Table I.

Mean dosages of injection midazolam and nalbuphine were 6 ± 2 mg, 7 ± 3 mg, respectively. In 19 patients (3.5%), the procedure was converted from conscious sedation to general anaesthesia because of agitation and restlessness despite maximum sedation (weight-based). Out of 550 procedures, only 2 (0.4%) reported complication of minor ampullary bleeding during sphincterotomy, which was managed endoscopically with injection of diluted adrenaline, none of the patients had post-ERCP severe pancreatitis or perforation. Details of therapeutics performed during procedure are shown in Table II. The study reports a success rate of 531 (96.5%) under conscious sedation. None of the patient had cardiopulmonary arrest or required any emergency intubation for airway maintenance. Patients were monitored for oxygen saturation and heart rate continuously, while blood pressure monitoring was done every five minutes during procedure, and 60 minutes post-procedure in recovery room.

DISCUSSION

This study determined that conscious sedation administered during ERCP procedure is not only safe but also feasible for gastroenterologists with insignificant incidence of procedure-related complications. Our study reported a success rate of 531 (96.5%) procedures. Our interpretations confirmed the findings of the previous

Table I: Basic demographics of patients.

Variables (n=550)	Mean \pm SD / Frequency (%)
Age (years)	50.85 \pm 15.66
Gender	
Male	197 (35.8%)
Female	353 (64.2%)
ASA	
I	268 (48.7%)
II	206 (37.4%)
III	76 (13.8%)
Duration of hospital stay (days)	2.42 \pm 1.41
Comorbid	
Hypertension	140 (25.5%)
Diabetes	62 (11.3%)
Ischemic heart	126 (22.9%)
Others	28 (5.1%)
Nil	189 (34.4%)
Associated symptoms	
Pain	
Generalized abdominal	209 (38%)
Right hypochondrial	11 (2%)
Epigastric	6 (1.1%)
Fever	85 (15.5%)
Jaundice	16 (2.9%)
Nausea	12 (2.2%)
Vomiting	61 (11.1%)
Chills	4 (0.7%)
Itching	2 (0.4%)
Weight loss	2 (0.4%)
Anorexia	1 (0.2%)
Diagnosis	
Choledocholithiasis	349 (63.4%)
Biliary stricture	117 (21.3%)
Biliary Leak	23 (4.2%)
Cystic duct stone	6 (1.1%)
Common bile duct stone and stricture	4 (0.7%)
Common bile duct worms	1 (0.2%)
Dilated common bile duct	14 (2.5%)
Periamullary growth	10 (1.8%)
Pancreatic duct stone	2 (0.4%)
Pancreatic duct leak	1 (0.2%)
Pancreatic duct disruption	2 (0.4%)
Normal examination	21 (3.8%)

Table II: Therapeutic during ERCP.

Variables	n	%
Sphincteroplasty		
Yes	36	6.5
No	514	93.3
Double wire technique		
Yes	21	3.9
No	529	96.1
Balloon sweep		
Yes	365	66.3
No	195	35.5
Outcomes		
Success	531	96.5
Failure	19	3.5
Stent		
Plastic	166	30.2
Metallic	61	11.1
Nil	323	58.7

studies.^{11,12} ERCP is an invasive and a time-consuming procedure and can cause discomfort to patients.¹³ Two of the most commonly encountered complications of this procedure are abdominal pain and hemorrhage. Hemorrhage is a complication more frequently associated with sphincterotomy rather than diagnostic ERCP.¹⁴ This study is also in accordance with other studies that reported similar findings. However, in the present study, frequency of hemorrhage was lower with only two reported cases.¹⁴⁻¹⁶

Risk factors for hemorrhage identified in multivariate analysis in a study included presence of a coagulopathy at the time of the procedure, administration of anticoagulants within 48-72 hours of the ERCP, the presence of acute cholangitis or papillary stenosis, etc.¹⁴⁻¹⁶ Hence, we can exclude hemorrhage as one of the complications associated with the administration of conscious sedation as it is common for patients to have procedure-related complications irrespective of the type of sedation or anesthesia used.

Morse *et al.* recommended administration of moderate sedation during the gastrointestinal endoscopy because it provides sufficient relief from pain with minimum adverse effects than deep sedation.¹⁷ In fact, many supporting studies have concluded that administration of conscious sedation by nurses or a gastroenterologist is a safe and effective method to reduce the cost of anesthesiologist-administered sedation.⁸⁻¹⁰

In contrast, few studies have concluded that gastroenterologist-directed sedation has similar efficacy and complication rate as those with anesthesiologist-directed sedation.^{17,18} In disagreement to the present study, some researchers have reported high physician satisfaction and more successful procedure rate under anesthesia. The major weakness of these studies is that it has not been controlled or lack blinding, which may contribute to research bias.¹⁹ The qualitative approach of this study has assured that we have assessed the range of safety of the ERCP procedure under conscious sedation.

CONCLUSION

It was observed that ERCP was safe under conscious sedation as it delivered balanced tranquillity.

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