

The dexmedetomidine “augmented” sedato analgesic cocktail: An effective approach for sedation in prolonged endoscopic retrograde cholangio-pancreatography

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Abstract

Background and Aims: In absence of any published standard guideline for sedation or anesthesia practice for prolonged therapeutic “endoscopic retrograde cholangio-pancreatography (ERCP),” safe and cost-effective sedation protocol is the need of the hour. Our study aims to evaluate the efficacy of a dexmedetomidine as an add-on for prolonged deep sedation for ERCP and to compare three deep sedation regimens regarding safety and efficacy.

Material and Methods: Forty-five consecutively enrolled patients planned for therapeutic ERCP and assumed to have prolonged procedural duration (>50 min) were divided into three groups in a randomized assessor blinded fashion. Group 1 received propofol and midazolam, Group 2 received the sedato-analgesic cocktail containing ketamine-propofol-midazolam-pentazocine, and the Group 3 received sedate-analgesic cocktail plus dexmedetomidine infusion under monitoring of vital parameters and according to the judgment of the concerned anesthesiologist. Total propofol requirement, episodes of gagging, oxygen desaturation, changes in mean blood pressure (MBP), recovery and satisfaction score of endoscopist, anesthetist and patient were noted and analyzed statistically using one way ANOVA with Bonferroni correction and Chi-square test.

Results: Mean propofol requirement, incidences of gagging and oxygen desaturation was significantly less in Group 2 and 3 compared to Group 1. MBP was more stable and recovery was faster in Group 3. Anesthetist’s satisfaction was more with Group 2 and even more with Group 3.

Conclusions: The sedato-analgesic cocktail was superior to the conventional propofol-midazolam regimen, dexmedetomidine as add-on increased the efficacy and safety of sedate-analgesic cocktail. It reduces propofol requirement, helps to maintain the patient in a safe and more stable level of sedation and increases satisfaction of the anesthetist.

Key words: Dexmedetomidine, endoscopic retrograde cholangio-pancreatography, ketamine, propofol, sedato-analgesic cocktail, sedation

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Introduction

Endoscopic retrograde cholangio-pancreatography (ERCP) has revolutionized the management of many biliary problems with its utility ranging from a diagnostic solution to complex therapeutic intervention. It is a complex procedure which requires expertise in the technique as well as adequate sedation and anesthesia. The choices are individualized and remain between moderate or conscious sedation, deep sedation, and complete general anesthesia.^[1] Failure rate and complications were found to be high with light sedation. General anesthesia was found to be safe, can alleviate many problems and associated with increased success. However, full general anesthesia is associated with increased use of resources, time and overall cost.

Deep sedation evolved as a better choice to get a good success rate.^[2] Propofol commonly, and also midazolam, fentanyl, ketamine, droperidol and number of other drugs had been used for this purpose either alone or in combination. Combinations of drugs may help to reduce dose of an individual agent. Thereby, dose related untoward effects by the individual agent may also be attenuated. Hemodynamic fluctuations and respiratory depression associated with deep sedation becomes alarming with the prone position of the patient during the procedure, with more serious consequences in the elderly patients. The line of demarcation between deep sedation and anesthesia is often faint raising the possibilities of respiratory and cardiovascular depression further.

Sedation and analgesia introduces an independent risk factor for morbidity and mortality in addition to the procedure itself.^[3] So due to obvious reason, if the duration of sedation is prolonged due to prolonged therapeutic procedure, risks will also be increased manifold. A sedato-analgesic cocktail described by Ong *et al.* was found to be a better choice than propofol sedation and may be useful choice in ERCP sedation.^[4] However, the efficacy of this regimen was not tested in deep sedation for prolonged therapeutic ERCP. Dexmedetomidine, the selective α -2 adrenergic agonist, though has sedative and analgesic role without major changes in respiratory parameters, was found inferior to propofol in ERCP sedation as a single agent.^[5] Still, the drug was able to gain popularity in different other types of procedural sedations, sedation in intensive care setting and also as an adjunct in anesthesia practice.^[6] The adjunctive role of dexmedetomidine to other sedative agents was however less studied in prolonged ERCP sedation and was not studied as an add-on to “sedato analgesic cocktail.” Hence in this pilot study, the conventionally practiced propofol regimen was compared to the “sedato-analgesic cocktail” and the “sedato analgesic cocktail” with dexmedetomidine “add on” in an attempt to find out a safer procedural sedation for prolonged therapeutic ERCP.

Material and Methods

The study was designed as a prospective, randomized, controlled, assessor blinded study comprising of 45 consecutively enrolled patients undergoing therapeutic ERCP with presumed duration 50 min or more. They were divided into three groups using web based randomization. As reference of study enrolling only prolonged ERCP with similar types of sedation regimens could not be found after extensive search in different search engines in the internet, the sample size was calculated from a pilot work on total 15 patients, 5 patients in each group. The deducted results (mean, standard deviation,

standard error etc.) were utilized in the sample size calculation. We have utilized level significance of 5% with a power of the study 80%.

All the cases were done inside a specialized operation theatre equipped with the basic supportive equipment and monitors. Permission of the Institutional Ethics Committee was obtained. Written informed consent was obtained from all the patients regarding their participation in the study. The study period was from April, 2011 to January 2012. All the patients enrolled were supposed to undergo therapeutic endoscopy and prolonged period of intervention of at least 50-60 min was anticipated.

The inclusion criteria was therapeutic ERCP patients supposed to have a prolonged procedural time of at least 50 min under sedation or total intravenous (IV) anesthesia, with age more than 50 years and in the ASA Grade I, II and III, who consented to participate in the study.

The exclusions were ASA IV or above, history of respiratory disease like asthma and chronic obstructive pulmonary disease, known allergy (to propofol and dexmedetomidine), not consenting to participate in the study and where general anesthesia was predecided for the procedure. Patients with severe arrhythmia, severe valvular stenosis, advanced cardiac failure, unstable angina, shock and recent myocardial infarction were excluded. Patients requiring conversion to general anesthesia or if the duration of the procedure was turned to be <50 min were excluded.

The demographic data related to age, sex, body weight, height, serum bilirubin, biochemical parameters, electrocardiogram (ECG) abnormality, arrhythmia, pre procedure blood pressure (BP), pulse rate and oxygen saturation (SpO₂) were noted.

Patients were divided into three groups according to the type of sedation they received. Group 1 received propofol with midazolam (served as control group), Group 2 received cocktail of ketamine, propofol with midazolam. Group 3 were given ketamine, propofol and midazolam with dexmedetomidine supplement. Group 1 and Group 2 patients received infusion of plain normal saline with syringe pump for blinding the assessor about administration of dexmedetomidine in Group 3.

Glycopyrrolate 0.2 mg IV was used as premedication in all patients. Midazolam was used in a dose of 1 mg IV at the beginning in the propofol group or Group 1, followed by propofol 0.75-1 mg/kg IV initially and then 10-20 mg IV as top up. The Group 2 received midazolam 0.5 mg,

pentazocine 6 mg, ketamine 25 mg IV at the beginning, followed by propofol 0.75-1 mg/kg IV initially followed by 10-20 mg top-ups. The Group 3 received dexmedetomidine infusion of 1 µg/kg for 7-10 min then 0.2-0.5 µg/kg/h for at least 30 min or more as judged by the anesthetist or if the procedure was prolonged for more than 1 h. Attempt was made to stop this infusion 15-20 min before the end of the procedure. Midazolam, pentazocine, ketamine and propofol were administered in the similar doses as that of Group 2. All the patients were turned to prone position and kept in such position throughout the procedure as per request of the endoscopist.

All the patients received oxygen by a bi-nasal prong since the beginning of the procedure till the end. Oxygen was continued postprocedure for a duration judged by the anesthetist. Any episode of oxygen desaturation was planned to be managed by increasing the flow of oxygen. Provisions were kept to deal with severe respiratory depression in the form of laryngeal mask airway, endotracheal tube and Boyles apparatus.

Depth of sedation was measured initially by using Ramsey Sedation Score and Richmond Agitation Sedation Scale (RASS).^[7-9] Patients were positioned after attaining a score of Ramsey 5 or RASS-4, the procedures started at RASS-5 (Unarousable). During the procedure depth of sedation was assessed by clinical monitoring in the form of checking for movement, response to verbal command, eyelash reflex, pupillary responses, tearing and pattern of respiration. The target RASS score was -5 during this phase and propofol top-up was given accordingly.

The primary efficacy parameter was total propofol use. Secondary efficacy parameters were oxygen desaturation; incidences of gagging; time of recovery; incidences of hypotension, satisfaction of the patient, endoscopist and the anesthetist.

Data from all the patients were recorded by an independent assessor who had knowledge of anesthesia, and did not actively participate in the anesthetic management.

The assessor, blinded about the group of the patient and drugs administered, noted down the number of gagging, episodes of respiratory depression, incidences of oxygen desaturation, intra-operative BP and pulse rate changes, incidences of arrhythmia or any other ECG changes and the duration of the procedure. Routine multichannel monitor were attached to all patient to note pulse rate, SpO₂, ECG, BP and respiration. However, physical counting of breath was also done periodically and apnoeic episodes were noted. Gagging episodes and movements by the patient during the procedure were counted physically. Postoperative recovery was also noted

by the assessor at every ten min after end of the procedure by using Aldrete scoring system. A value of 9 or more was considered as discharge criteria. Psychomotor analysis was performed after attaining an Aldrete score 8 or more. At the end of the procedure overall satisfaction of the endoscopist and anesthetist were recorded using a 100 mm Visual Analog Scale (VAS). At discharge, the patient's satisfaction was also noted using similar VAS. The drugs and doses were noted at the end from the anesthetic record sheet.

Respiratory depression was defined as respiratory rate eight or below per minute or if there is episode of oxygen desaturation (if SpO₂ was below 85%). All cases of respiratory depression was considered here as oxygen desaturation. Hypotension was defined as decrease in BP by 20% or more of the baseline or systolic BP (SBP) of 90 mm in Hg or less or mean BP (MBP) of <60 mm in Hg. Hypertension was defined as an increase in BP 20% or more of baseline or SBP 150 mm in Hg or MBP more than 100 mm in Hg. Similarly tachycardia and bradycardia was denoted for rise in heart rate by 20% or more or a value above 100/min and fall of heart rate by 20% or more from baseline or 50/min respectively. Duration of the procedure was from the time of insertion of the endoscope till taking it out finally. Adverse events were monitored till the discharge of the patient.

Collected data were analysed statistically using one way ANOVA and Chi-square test using SPSS for Windows, Version 16.0 (SPSS Inc., Chicago, USA) and Open Epi version 3.0 statistical software (Dean AG, Sullivan KM, Soe MM. OpenEpi: Open Source Epidemiologic Statistics for Public Health, Version. www.OpenEpi.com, updated 2014/09/22, accessed 2015/02/24). *Post-hoc* test was done to find out difference between individual groups using Bonferroni correction and $P < 0.05$ was considered statistically significant.

Results

The baseline demographic parameters were comparable in the three groups [Table 1].

Mean propofol use was significantly less in Group 2 and Group 3 [Table 2]. Post hoc analysis revealed that propofol consumption was significantly less in Group 2 compared to Group 1 and the same was significantly less in Group 3 in comparison to both Group 1 and 2. Gagging and oxygen desaturation were less in Group 3 compared to Group 1, however there was no statistically significant difference between Group 2 and 3. Most of the episodes of respiratory depression were noted in Group 1. Recovery was faster in Group 2 and 3 compared to Group 1, but there was no statistically significant difference between Group 2 and 3.

Satisfaction of the endoscopist, anesthetist and the patient were shown in Table 3. Satisfaction of the anesthetist was significantly more in Group 3. Endoscopist’s satisfaction was also higher in Group 3, but patient’s satisfaction was similar among the groups.

Changes in MBP were minimal and more predictable in Group 3 patients [Figure 1]. Ketamine induced rise in BP was not noted in this group.

Discussion

In this study, all three regimens were successful as a method of sedation for ERCP. However Group 2 and 3 patients scored better in terms of mean propofol use, less respiratory depression and oxygen desaturation, better hemodynamic stability, less gagging and faster recovery. Again, Group 3 scored better than Group 2 in most of the parameters other than recovery time which was comparable in both groups. All the differences did not reach the level of statistical significance due to small sample size.

Propofol, a popular agent for day care surgery, is known for its early recovery and additional antiemetic property. Propofol could be effectively used for ERCP sedation.^[10,11] However, hypotension is associated with use of propofol.^[12] Therapeutic ERCP takes longer duration of sedation and so a higher quantity of propofol is required to produce adequate procedural sedation. Longer duration of deep sedation with a higher dose of propofol usually accompanies with respiratory depression with suppression of cough and gag reflexes. Along with above mentioned disadvantages, unavailability of any antagonist to such actions of propofol raised the question of suitability of propofol for routine use in ERCP.^[13] Variation in the depth of sedation was another problem with ultra-short acting agents like propofol requiring constant titration of dose.^[4] Seifert *et al.* found that use of midazolam with propofol was associated with less requirement of propofol, but quality of sedation was similar to propofol alone and recovery was prolonged.^[14]

Use of different cocktail sedation or anaesthetic techniques are proposed by different researchers as an effective mean of sedation for ERCP. Often they were found superior to individual agent in the form of safety and stability of the patient during the procedure.^[4,15]

Ketamine, the phencyclidine derivative, is known to produce dissociative anesthesia, has analgesic, amnestic and BP elevating property.^[16] It was found to reduce propofol requirement when co-administered to propofol. Incidences of hypotension were also low with this regimen compared to propofol alone.^[17]

The “sedato-analgesic cocktail” described by Ong *et al.*, was found to be an effective deep sedation regimen for ERCP with

Table 1: The baseline parameters

Parameter	Group 1	Group 2	Group 3	P
Age (years)	61.93±3.8	64±8.4	62.07±10.03	0.72
Gender (male/female)	7/8	6/9	7/8	0.91
Weight (kg)	61.4±6.8	61.27±7.3	65.13±5.6	0.2
Height (cm)	167.73±8.5	165.53±7.2	171±8.07	0.18
Bilirubin (mg/dl)	5.36±1.53	6.06±11.44	6.1±0.99	0.23
Baseline mean BP	100.26±5.45	102.68±4.61	105.02±5.95	0.06

Values expressed as mean ± SD. SD = Standard deviation, BP = Blood pressure

Table 2: The variation of propofol use and other parameters amongst three groups

Parameter	Group 1	Group 2	Group 3	P
Duration (min)	86.33±14.445	80±17.2	84±16	0.55
Propofol (mg)	452±61.2	389±50.2	196±28.7	<0.001
Recovery time (min)	37±7.7	29±6.86	29±8.9	0.01
Gagging (n)	1.4±1.54	0.8±1.08	0.13±0.35	0.12
Oxygen desaturation (n)	1.6±1.4	0.8±1.08	0.13±0.35	0.002
Vomiting (n)	0.13±0.35	0.13±0.35	0.07±0.25	0.81

Values expressed as mean ± SD. SD = Standard deviation

Table 3: The satisfaction scores among endoscopist, anesthetist and the patient

Parameter	Group 1	Group 2	Group 3	P
Endoscopist’s satisfaction (VAS score)	7.3±1.36	7.57±1.1	8.4±1.05	0.05
Anesthetist’s satisfaction (VAS score)	7.3±0.92	8.07±1.1	9.07±0.26	<0.001
Patient’s satisfaction (VAS score)	8.77±0.79	9.07±0.59	8.87±1.12	0.63

Values expressed as mean VAS + standard deviation. VAS = Visual analog scale

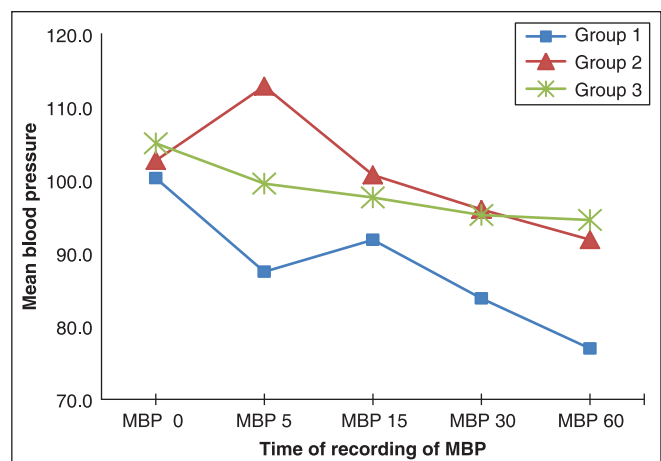


Figure 1: Changes in blood pressure during the procedure

reduced propofol requirement. They employed pentazocine along with ketamine, propofol and midazolam. Synergistic effect of the agents in this cocktail was proposed to be the cause of less propofol requirement. Less variability in patient behavior, less requirement of propofol, less number of “top-up” doses with a more “balanced” sedation with a gradual reversal was some key features of this regimen. The low dose of ketamine used here in combination with propofol and midazolam was not associated with neurophysiological changes at emergence that are common with ketamine. But a higher frequency of oxygen desaturation during the induction period was noted in the patients receiving this cocktail.^[4] The pattern of changes in BP was not mentioned in this study. The mean procedure duration in this study was 14.8-17.1 min in two groups of patients of both diagnostic and therapeutic ERCP. Therefore, the efficacy of this regimen was not really tested in prolonged duration ERCP.

Dexmedetomidine is a novel α -2 adrenergic agonist, which as an adjuvant produces profound sedation without appreciable respiratory depression in volunteers.^[18] The α -2-mediated reduction in sympathetic tone attenuates the hemodynamic response to intubation and extubation.^[19,20] The stress response to surgery is also reduced.^[21] It provides cardiovascular stability, and so might protect against ischaemia, a property independent of its sedative properties.^[22] Absence of respiratory depression again was documented in the post-surgical patients in the intensive care setting in the doses that provide adequate analgesia and sedation.^[23] In combination with ketamine, it reduces ketamine requirement, suppress the cardio-stimulatory effect of ketamine and produces less anterograde amnesia than midazolam.^[24] As a single agent, dexmedetomidine was found effective in producing conscious sedation for diagnostic ERCP with mean procedural duration <26 min.^[25] However, as a single agent, dexmedetomidine was inferior to propofol in producing conscious sedation in ERCP patients.^[5] The present study attempts exploring dexmedetomidine for its adjunctive analgesic, sedative and cardio-protective action, and so it was added to the “sedato-analgesic cocktail.”

In the present study, procedural sedation in all the cases was performed by trained anesthetist in operation theatre setting with intensive care back up. The plan of rescue for patients with significant and persistent oxygen desaturation, not manageable by simple measure and nasal oxygenation, were endotracheal intubation and conversion to complete general anesthesia under controlled ventilation. However, the observed oxygen desaturations in this study were transient and were managed by simple maneuvers like neck extension and increasing the flow of oxygen in the nasal prong. None required laryngeal mask airway or endotracheal intubation.

The anesthetist was not blinded and allowed to take free decision regarding the dose of propofol and other emergency medications. However, the patients, endoscopist and the assessor were blinded to reduce bias in the study.

The present study validates the findings of Ong *et al.* regarding the superiority of the sedato-analgesic cocktail over propofol in prolonged sedation for therapeutic ERCP. It also suggests that augmentation of this cocktail regimen with dexmedetomidine was superior to the “sedato analgesic cocktail.” The prolonged duration of sedation even in prone position resulted in minimal changes in the vital parameters of this group of patients. However, the recovery characteristic was similar to that of the sedato analgesic cocktail.

Though this is one of the pilot studies including only the therapeutic ERCP with prolonged duration in “relatively older” patients (>50 years) and comparing multiple regimens, few weaknesses necessitates further studies in this regard. Small sample size is one of the limitations of the study. A possibility of bias was there in the form of reduced propofol administration by the nonblinded anesthetist. Also, there was no effective means of studying the depth of sedation and there was no clear cut division between assessing deep sedation and anesthesia. So, future studies with larger sample size and assessment of the sedation level with monitoring like “Bi-spectral index” might be considered.

Conclusions

Expectedly, the sedato analgesic cocktail of propofol-midazolam-ketamine was found superior to propofol in ERCP sedation for prolonged duration validating the finding of the previous researcher. Dexmedetomidine “augmented” sedato analgesic cocktail was significantly superior to the sedato analgesic cocktail of propofol-midazolam-ketamine and propofol sedation in ERCP. The “augmented” regimen offered better patient stability, reduced propofol requirement, minimum variability in sedation level, higher anesthetist’s and Endoscopist’s satisfaction.

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