International Journal of Recent Advances in Multidisciplinary Topics
Volume 2, Issue 9, September 2021
https://www.ijramt.com | ISSN (Online): 2582-7839

A Study to Evaluate Efficacy and Complications of Deep Sedation Technique for Endoscopic Retrograde Cholangiopancreatography

Pooja Thaware[1*], Prabha Rashmi[2], Saurabh Trivedi[3]
[1,2,3]*Senior Resident, Department of Anesthesiology and Critical Care, All India Institute of Medical Sciences, Bhopal, India*

***Abstract*: *Background and Aims*: We studied the efficacy and complications of deep sedation technique for Endoscopic retrograde cholangiopancreatography. Material and Methods: Adults patients from either gender aged 18 to 60 years (n = 60), American society of Anesthesiologists (ASA) physical status grade I and II undergoing ERCP. Patients are premedicated with glycopyrrolate 0.004 mg/kg intravenously (iv), midazolam 0.02 mg/kg/iv, fentanyl 2 µg/kg iv and sedation is induced with propofol 1 mg/kg iv with ketamine 0.5 mg/kg iv and received a loading dose of dexmedetomidine 1 µg/kg over 10 min followed by maintenance dose at 0.5 µg/kg/hr. Ramsay Sedation Scale (RSS) of 5 was considered an acceptable level for starting ERCP. Rescue Propofol 0.5 mg/kg IV was given whenever patient becomes uncomfortable or moves during the procedure. The Statistical software namely SPSS 18.0, and R environment version 3.2.2 were used for the analysis of the data. *Results*: Initiation of ERCP was 100% prosperous with median induction time of 10 min. Maintenance of sedation was prosperous in 100% with dexmedetomidine. After induction and giving loading dose of dexmedetomidine over 10 min, mean heart rate and blood pressure showed statistically paramount fall (P value: P<0.001) but patients were hemodynamic ally stable. We optically canvassed gagging, hypotension and bradycardia as intraprocedural adverse events in 7, 14 and 4 patients respectively. The mean time for recovery after ERCP procedure till patients achieve Modified Aldrete score (MAS) of 9 or above was 18.25±4.86 min. *Conclusion*: After premedication with glycopyrrolate 0.004 mg/kg/iv, midazolam 0.02 mg/kg/iv, fentanyl 2 µg/kg iv induction of deep sedation with propofol 1 mg/kg, ketamine 0.5 mg/kg, and loading dose of dexmedetomidine 1µg/kg over 10min provide good conditions for initiation of ERCP and prosperous maintenance on dexmedetomidine 0.5 µg/kg/hr and rescue doses of propofol 0.5 mg/kg without consequential adverse events and more resilient recovery.**

***Keywords*: Deep sedation, Dexmedetomidine ERCP, Ramsay Sedation Scale.**

1. Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is an intricate gastrointestinal procedure. It is highly efficacious implement to diagnose or treat a variety of biliopancreatic diseases. Since its prelude in 1968, ERCP has evolved from being a simple diagnostic procedure to becoming a therapeutic one of incrementing duration and intricacy, requiring high degree of patient co-operation. Ideal sedation for ERCP should maximize patient comfort and safety and minimize pain, discomfort and stress which occurs during ERCP. However ERCP performed under conscious sedation, patient comfort is compromised in the interest of safety. Albeit conscious sedation was the mainstay for most endoscopic procedures over the initial decenniums of endoscopy, anesthesia accommodations have increasingly been utilized over recent years to provide deeper levels of sedation. There are number of drugs which are utilized for this purport such as propofol, dexmedetomidine, fentanyl, ketamine, midazolam etc. Coalescence of drugs avail to minimize dose of an individual agent thereby dose cognate deleterious effects of the drug can be attenuated. Sedation with coalescence of drugs has been increasingly utilized for many gastrointestinal procedures including ERCP because there are numerous benefits like amended patient compliance, ameliorated patient gratification, abbreviated procedural time and consequently amended efficiency of endoscopy units. In this study we will evaluate the efficacy and complications of deep sedation technique for ERCP procedure.

2. Material and Methods

This prospective non-randomized controlled study was conducted in the endoscopic suite of a tertiary care institution. The study was approved by institutional ethics committee. Exhaustive history was obtained. The adult patients (n= 60) of 18–60 years of age, American Society of Anesthesiologists (ASA) physical status grade I or II underwent ERCP were included in the study. Patients with ASA grade III and IV and patients who are allergic to any of the drugs utilized in the study were omitted from the study. An inscribed apprised consent was obtained from the patient afore starting the procedure. Patients were taken for the ERCP procedure in the endoscopy room after corroborating adequate starvation of 8 hour. Pulse oximeter, cardioscope and a noninvasive blood pressure cuff was applied. Patient's baseline heart rate (HR), systolic blood pressure (SBP) and diastolic blood pressure (DBP) and oxygen saturation

*Corresponding author: pthaware20@gmail.com

(SpO2) was recorded. Oxygen was supplied by nasal prongs at the rate of 4L/min. Intravenous line was secured on dorsum of right hand and intravenous fluid ringer lactate was commenced at the rate of 1 ml/kg/hr.

Premedication is given with Inj glycopyrrolate 0.004 mg/kg/IV, Inj midazolam 0.02 mg/kg/IV, Inj fentanyl 2 microgram/kg/IV. Then patient was sedated with Inj propofol 1 mg/kg/IV (1ml of 1% lignocaine added to every 10 ml of propofol to decrease pain on injection) and Inj ketamine 0.5 mg/kg IV. Dexmedetomidine infusion was started at loading with 1microgram/kilogram of body weight over 10 minute. At the end of 10 min dexmedetomidine infusion is given at maintenance dose of 0.5 microgram/kg/hour. Then the patient was given left lateral position. During the procedure to maintain Ramsay Sedation Scale (RSS) of 5-6 (Sluggish response to light glabellar tap or loud auditory stimulus - No response to light glabellar tap or loud auditory stimulus) when the patient becomes uncomfortable the rescue intravenous (IV) sedation was given with top up doses of propofol 0.5mg/kg IV. Ramsay Sedation Scale was assessed during the procedure. At the terminus of 10 min after giving loading dose of dexmedetomidine heart rate (HR), Systolic and Diastolic Blood Pressure (SBP and DBP), oxygen saturation (SpO2), Ramsay sedation scale (RSS) were recorded and then readings were noted every 5 minute till the ERCP procedure is consummated. Any complication occurring during the ERCP procedure like gagging, coughing, hypotension (fall in SBP more than 20% of baseline), hypertension (increase in SBP more than 20% of baseline), bradycardia (HR <60beat/min), arrhythmia, hypoxia (fall in oxygen saturation less than 95%), nausea, regurgitating, shivering were noted.

Bradycardia less than 60/min was vigilantly monitored, and bradycardia less than 50/min were treated with inj atropine 0.6mg IV. Hypotension (fall in SBP more than 20% of baseline) was treated with 100 ml bolus of IV fluid ringer lactate. If hypotension persists, another 100 ml bolus of IV fluid ringer lactate was given. If hypotension persists further, inj ephedrine 6 mg was given and reiterated if required. Fall in oxygen saturation below 95% was treated with incrementing flow of oxygen to 8L/min and chin lift maneuver. Fall in oxygen saturation below 90% mandate abstraction of endoscope and bag mask ventilation with 10L/min oxygen flow. If patient gagged or coughed, 10 mg IV propofol boluses were given to deepen plane of sedation. To assess recovery time patient was evaluated every 5 min after the procedure till the Modified Aldrete score (MAS) reaches 9 or above (Able to cough freely and breathe deeply, Able to maintain SpO2 >92% on room air, Fully awake or arousable on calling, BP +/- 20% of pre-anaesthetic level, Able to move all 4 or extremities voluntarily or on command).

3. Results

This study was conducted over 18 months in 60 patients of 18 to 60 years undergoing endoscopic retrograde cholangiopancreatography under deep sedation. The main indications were cholangitis, choledocholithiasis and blocked stents. Among 60 patients only 1 patient was below 20 years of age, 16 patients were between 21 to 30 years, 14 patients were between 31 to 40 years, and 16 patients were above 50 years and less than 60 years. Out of 60 patients 40% were ASA grade I and 60% were ASA grade II patients. The time duration of ERCP procedure was ranging from 25.00 to 60.00 min, with average time being 35.33±8.58 min.22 (36.7%)ERCP procedure were of time duration up to 30 min. 34 (56.7%) ERCP procedure were of time duration between 30 to 45min (out of which 20 procedures were of 35 min, 4 procedures were of 40 min and 10 procedures were of 45 min), 4 (6.7%) ERCP procedure was of time duration between 45 to 60 min. After induction and giving loading dose of dexmedetomidine over 10 min, till the terminus of 50 minutes mean heart rate, systolic and diastolic blood pressure showed statistically consequential fall (P value: P<0.001)but patients were hemodynamically stable. Throughout the procedure mean SPO2 did not showed any paramount change till the terminus of the procedure. We endeavored to keep Ramsay sedation scale of 5 during the procedure. The mean of total quantity of rescue drug propofol used during ERCP procedure was 44.67±30.27 mg. Out of 60 patients 22 patients (36.7%) required<40mg of rescue drug propofol, 34 patients (56.7%) required up to 80 mg and 4 patients (6.7%) required more than 80 mg.120mg was the maximum quantity of rescue drug used and was utilized only in two patients. The most common intraoperative complication was hypotension (fall in systolic or diastolic blood pressure >20% of baseline) occurred in 14 patients (23.3%).Gagging occurred in 7 patients (11.7%), bradycardia (heart rate <60/min) occurred in 4 patients (6.7%).There was no episodes of hypoxia, hypertension, coughing, arrhythmia, regurgitating, shivering or any other complication in any of the patients. The mean time for instauration after ERCP procedure till patients achieves Modified Aldrete score of 9 or above was 18.25±4.86 min.

4. Discussion

A perpetuated and uncomfortable endoscopic procedure like ERCP requires expertise in the technique as well as adequate sedation. The choice of anesthesia for ERCP remains between conscious sedation, deep sedation, and general anesthesia. ERCP is a procedure that requires a relatively motionless patient. Complications and failure to consummate the procedure were found to be high with inadequate sedation. General anesthesia is safe but it has its own complications. Deep sedation has evolved as a better choice with a good prosperity rate. Jeurnink et al have found in their study that among 139 patients one-third to one-a moiety of patients experience pain and discomfort during and immediately after ERCP when it is performed with conscious sedation. On the other hand general anesthesia or deep sedation with propofol may well abbreviate the encumbrance of ERCP, concretely for patients with younger age, or therapeutic ERCP treatment [1]. A single agent for sedation for ERCP results into increase in dosage of that single agent and additionally increases sedation cognate complications [2]. Coalescence of drugs decreases the dose of an individual agent. Thus dose related unpropitious effects by the individual agent can be attenuated.

Mukhopadhyay et al studied the efficacy of dexmedetomidine as an integrate-on to propofol for perpetuated deep sedation for ERCP [3]. The sedative analgesic cocktail they used contained ketamine propofol midazolam pentazocine plus dexmedetomidine infusion. Desaturation was significantly less and blood pressure was more stable and recovery was more expeditious, additionally the sedative analgesic cocktail truncates propofol requirement [3, 4].

Midazolam has sedative, amnesic, and anti-solicitousness effects, but no analgesic effect. Midazolam is preferred to other benzodiazepines because it is dihydrogen monoxide-soluble, does not cause venoirritation or pain on injection, is expeditious-acting, and has a relatively short-elimination half-life of about 2 to 4 hours. Propofol is a lipophilic intravenous short-acting anaesthetic agent which is most prevalent drug utilized in ERCP. Propofol has sedative and amnesic effects, but no analgesic effect. Administering high doses of propofol to deepen the anaesthesia leads to cardiovascular dejection. Consequently integrating low doses of other drugs such as ketamine, fentanyl, dexmedetomidine decreases the dose of propofol and thus decrease deleterious effects cognate to its higher doses. Fentanyl is a synthetic opiod that is often utilized with midazolam for sedation and analgesia in ERCP. The additament of pre or intraprocedural opioids had no effect on propofol requisite for deep sedation, but patients who received fentanyl had less pain [5]. Administration of propofol in cumulation with an opioid truncates the total dose of propofol. Propofol opioid cumulation provided efficacious and reliable sedation, increases the practitioner gratification, decreases the pain level, and provides hemodynamic stability compared to the administration of propofol alone [6].

Ketamine is a non-barbiturate short-acting intravenous anaesthetic agent that causes dissociative anaesthesia. Low dose (0.5 mg/kg) has acceptable analgesic and hypnotic effects and withal causes less respiratory depression with fewer cardiac complications. Ramkiran S et al concluded that ketamine with background propofol boluses resulted in propitious hemodynamic [5]. Dexmedetomidine is an α-2 adrenergic agonist which as an adjuvant engenders profound sedation without appreciable respiratory depression. It provides cardiovascular stability and has analgesic property. Lee et al studied midazolam with meperidine and dexmedetomidine versus midazolam with meperidine for sedation during ERCP. They had concluded that the integration of dexmedetomidine to the midazolam-meperidine regimen provided better sedative efficacy and a superior safety profile during ERCP compared with a midazolam-meperidine regimen [6].

In our study, we maintained Ramsay Sedation scale equal and above 5. All patients were hemodynamically stable. There is consequential fall in heart rate, systolic and diastolic blood pressure following induction till 45 min of procedure but all patients were clinically stable. Oxygen saturation is well maintained 97% and above throughout the procedure. The procedure could be consummated in all of the patients without any interruption. Hypotension was the most common complication followed by gagging and bradycardia. There was no episode of hypoxia in any of the patients with good recovery profile. Limitation of the study: The biasing chances are high as it was a non-randomized study.

5. Conclusion

ERCP which is a perpetuated, involute and uncomfortable procedure mandates deep sedation for patient's cooperation and prosperous completion of the procedure without any complications which can occur with moderate sedation levels. From our study we conclude that deep sedation technique utilizing propofol, dexmedetomidine, ketamine with midazolam and fentanyl for endoscopic retrograde cholangiopancreatography is efficacious and safe under vigilant monitoring for ASA I and II patients with less complications. There was less variation in sedation level with good recovery profile and more preponderant patient cooperation.

Financial support and sponsorship: Nil.
Conflicts of interest: There are no conflicts of interest

References

[1] Jeurnink, S. M., Steyerberg, E. W., Kuipers, E. J., & Siersema, P. D. The burden of endoscopic retrograde cholangiopancreatography (ERCP) performed with the patient under conscious sedation. Surgical Endoscopy, vol. 26, no. 8, pp. 2213–2219, 2012.

[2] Paspatis, G. A., Manolaraki, M. M., Vardas, E., Theodoropoulou, A., & Chlouverakis, G. (2008). Deep sedation for endoscopic retrograde cholangiopancreatography: intravenous propofol alone versus intravenous propofol with oral midazolam premedication. Endoscopy, vol. 40, no. 4, pp. 308–313, 2008.

[3] Mukhopadhyay, S., Niyogi, M., Sarkar, J., Mukhopadhyay, B., & Halder, S. (2015). The dexmedetomidine "augmented" sedato analgesic cocktail: An effective approach for sedation in prolonged endoscopic retrograde cholangio-pancreatography. Journal of Anaesthesiology Clinical Pharmacology, vol. 31, no. 2, pp. 201, 2015.

[4] Ong, W., Santosh, D., Lakhtakia, S., & Nageshwar Reddy, D. (2007). A randomized controlled trial on use of propofol alone versus propofol with midazolam, ketamine, and pentazocine "sedato-analgesic cocktail" for sedation during ERCP. Endoscopy, vol. 39, no. 09, pp. 807–812, 2007.

[5] Fassoulaki, A., Iatrelli, I., Vezakis, A., & Polydorou, A. (2015). Deep sedation for endoscopic cholangiopancreatography with or without pre or intraprocedural opioids. European Journal of Anaesthesiology, vol. 32, no. 9, 602–608, 2015.

[6] Haytural, C., Aydınlı, B., Demir, B., Bozkurt, E., Parlak, E., Dişibeyaz, S., Saraç, A., Özgök, A., & Kazancı, D. (2015). Comparison of Propofol, Propofol-Remifentanil, and Propofol-Fentanyl Administrations with Each Other Used for the Sedation of Patients to Undergo ERCP. *BioMed Research International*, pp. 1–5, 2015.

[7] Ramkiran, S. BIS Targeted Propofol Sparing Effects of Dexmedetomidine Versus Ketamine in Outpatient ERCP: A Prospective Randomised Controlled Trial. *Journal of Clinical and Diagnostic Research.* 2015.

Lee, B., Ryu, J., Lee, S., Lee, M., Jang, S., Hwang, J.-H., Ryu, J., Do, S.-H., & Kim, Y.-T. Midazolam with meperidine and dexmedetomidine vs. midazolam with meperidine for sedation during ERCP: prospective, randomized, double-blinded trial. Endoscopy, vol. 46, no. 04, pp. 291–298, 2014.