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Sedation for Endoscopic Retrograde Cholangiopancreatography in Elderly Patients – the Effect of Intravenous Lidocaine Infusion. A Randomised, Double-Blind, Placebo Controlled Trial

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ABSTRACT

Background: Sedation of elderly patients with associated comorbidities, subjected to ERCP procedure, can produce serious complications including respiratory instability and hemodynamics caused by the administration of anesthetic substances. In this study we aimed to evaluate whether the administration of lidocaine in continuous infusion during ERCP procedure reduces the consumption of propofol and the rate of complications in these patients.

Methods: 83 patients over 65-year old, ASA II-IV score, undergoing an ERCP procedure were randomized in two groups: lidocaine group (group L) who received 1.5 mg/kg lidocaine 1% and propofol 1mg/kg at induction and then 2 mg/kg lidocaine 1% in continuous infusion during the procedure and control group (group C) who received saline in the same amount as group L and propofol 1mg/kg. The consumption of propofol, intraprocedural complications, the time of awakening and recovery, the quality of postprocedural analgesia, the satisfaction of the endoscopist were registered.

Results: Propofol consumption was statistically significantly lower in group L compared to group C [135.37 (±43.23) vs. 214.88 (±51.83), p=0.001]. The same result was obtained related to the awakening time [2.85 (±1.50) vs. 5.38 (±1.36), p=0.001] and recovery time [23.90 (±12.66) vs. 26.17 (±12.41), p<0.001], the episodes of intraprocedural desaturation (p=0.001), the involuntary intraprocedural movements (p=0.001), the endoscopist's satisfaction (p=0.006). No differences were found in terms of post-procedure pain scores (p=0.54).

Conclusions: Lidocaine can be administered to reduce the need for propofol, faster awakening and lower intraprocedural complications in elderly patients undergoing the ERCP procedure.

Key words: endoscopic retrograde cholangiopancreatography – sedation – lidocaine – propofol – elderly.

Abbreviations: ASA: American Society of Anesthesiology; BMI: body mass index; ERCP: endoscopic retrograde cholangiopancreatography; EtCO2: end-tidal carbon dioxide; MAC: monitored anesthesia care; SpO2: oxygen saturation; VAS: visual analogue scale.

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is a complex endoscopic procedure, practiced in patients with biliary or pancreatic tract pathology. It is a procedure with a relatively long duration, demanding for the endoscopist and traumatic for the patient [1]. For the success of the procedure, it is necessary that the patient does not move, as the patient's movements can lead to complications or failure of the procedure. For this reason, the procedure requires the administration of some type of sedation or anesthesia, so that the patient can tolerate the intervention. The most used technique to ensure patient comfort is deep sedation under the supervision of an anesthesiologist, monitored anesthesia care (MAC) [1-3]. Propofol is the most used hypnotic agent administered during the ERCP procedure due to its rapid action and reduced half-life, allowing a rapid awakening. However, propofol has a narrow therapeutic index; patients can quickly switch to very deep sedation levels accompanied by complications such as airway obstruction, apnea, hypoxia, hypotension [4-7]. These complications are more pronounced in elderly and fragile patients with multiple comorbidities, a category found more and more frequently in the interventional endoscopy compartments. Benzodiazepines

or opioids have been used in an attempt to reduce the dose of propofol, but they can also cause respiratory complications [8-10]. Lately, studies shown that the intravenous administration of lidocaine had analgetic, anti-inflammatory effects, decreased the consumption of opioids and reduced the consumption of propofol by up to 50% [11]. In this regard, lidocaine administered intravenously in ERCP procedures and especially in elderly patients with associated comorbidities, could reduce the consumption of propofol and the complication rate.

The purpose of this study was to evaluate the effectiveness of continuous administration of intravenous lidocaine on the consumption of propofol in elderly patients undergoing ERCP procedure. Secondary outcomes were the side effects, the quality of sedation, the satisfaction of the endoscopist, the times of awakening and recovery after the procedure and post-procedural pain.

METHODS

This prospective, randomized, double-blind, placebo-controlled study was conducted between February 2022 and April 2022 in the Endoscopy Department of the Prof. Dr. Octavian Fodor Regional Institute of Gastroenterology and Hepatology, Cluj-Napoca, Romania. The methodology was approved by the Ethics Committee of our hospital (5558/2022) and the study was registered on the clinicaltrials.gov (NCT05274984).

All patients studied signed informed consent and were given details about the study and the evaluation of pain scores.

We included patients between 65-95 years, with American Society of Anesthesiology (ASA) scores I-IV scheduled for ERCP. The exclusion criteria were patients under 65 years of age, those with renal, hepatic or severe cardiovascular disease, hypoxic patients [oxygen saturation (SpO_2<94%) in atmospheric air], hypotensive [mean arterial pressure < 55mmHg), uncontrolled hypertensive (mean arterial pressure > 130mmHg), those with a history of allergy to lidocaine and those who could not sign informed consent.

According to the institutional protocol, patients were taken to the endoscopy unit after six hours of fasting and were given 6 ml/kg/hour crystalloid intravenously (i.v.). Half an hour before procedure patients received 1 gram of ceftriaxone as a prophylactic antibiotic. They received prophylactic rectal indomethacin. The patients were not premedicated with benzodiazepines or opioids before procedure so that the propofol dose would not be influenced by premedication.

Demographic data, such as age, gender, and body mass index (BMI) were recorded for each patient. Diagnosis, procedure indication, duration, and ASA classification were also noted.

The patients were randomly allocated into two groups: lidocaine group (Group L) and control group (Group C) at a ratio of 1:1 using a computer-generated sequence. Drugs were prepared by a nurse and administered by the anesthetist. Only the investigator and the nurse who prepared the drugs knew patient assignments. Patients, endoscopist, anesthetist, and data collection observers were all blinded to the group allocation. All ERCP procedures were performed by the same anesthesiologist and 5 highly experienced endoscopists at the endoscopy unit. With patients in a prone position, 4 L/min oxygen via a nasal cannula was supplied.

Noninvasive blood pressure was measured at 5- minute intervals automatically. End-tidal carbon dioxide ($EtCO_2$) and respiratory rate were monitored with a capnograph. SpO_2, heart rate and electrocardiography were continuously monitored. Hypotension was defined as a 15% decrease in mean arterial pressure compared to the basal value. Desaturation was defined as SpO_2 < 94%. Patients in group L received 1.5 mg/kg lidocaine 1% 5 min before procedure and then 2 mg/kg/h continuous infusion of lidocaine 1%. The controls received an equal volume of saline solution having the same color as lidocaine so it could not be identified by the anesthetist in charge of the procedure. All patients received a bolus dose of 1 mg/kg then 10-20 mg i.v. boluses during the procedure guided by capnograph monitoring and the patient's grimace, mobility, hemodynamic changes. In both groups, in case of uncontrolled hypertension, tachycardia, sweating 25 mcg of fentanyl was administered as rescue analgetic.

At the end of the procedure, the total amount of propofol was noted. It was also noted the awakening time defined as the time from the withdrawal of the endoscope until the patient opened his eyes, the recovery time defined as the time until the patient had an Aldrete score of 9, when the patients were sent to the wards. Postoperative analgesia was assessed using a visual analogue scale (VAS) (VAS=0 meaning no pain, VAS=10 meaning the most severe pain that can be felt). After the procedure, VAS scores were recorded at 5 and 45 minutes. Signs of lidocaine toxicity such as tinnitus, numbness of the tongue and lips, nausea, vomiting arrhythmias, metallic taste were watched for another 2 hours post-procedural. The satisfaction of endoscopists was evaluated on a scale of 1 to 4 (poor, moderate, good, and excellent).

Statistical Analysis

For this study, a sample size of 38 patients/group was calculated for a study power of 85%. This sample size was calculated based on a pilot study that indicated a consumption of propofol in the group C of 240±60mg (N=10) and in the group L of 150±40 mg. Considering the possible losses, we decided to include 40 patients per group and in the end the statistical analysis was made from 83 patients. The statistical data was collected using Microsoft Excel 2019 and was later interpreted using the IBM SPSS v26.0 program. To compare the mean values between the two samples, the t-test for independent samples was used. To observe the existence of a link between two dichotomous qualitative variables, the Pearson Chi Squared test, or Fisher test, was used. The statistical materiality threshold was considered to be $p<0.05$.

RESULTS

The demographic data of the patients in the study are presented in Table I. The Consort diagram is showed in Fig. 1.

The average age of the patients was 74.73 (±7.92) in group L and 72.62 (±5.88) in group C without statistical significance. In group L there were statistically significantly more female patients than in group C (82.9% vs. 17.1% p=0.001). The diagnosis of cholelithiasis was more frequent than the diagnosis of neoplasia in group L (82.9% vs. 17.1% p<0.001).

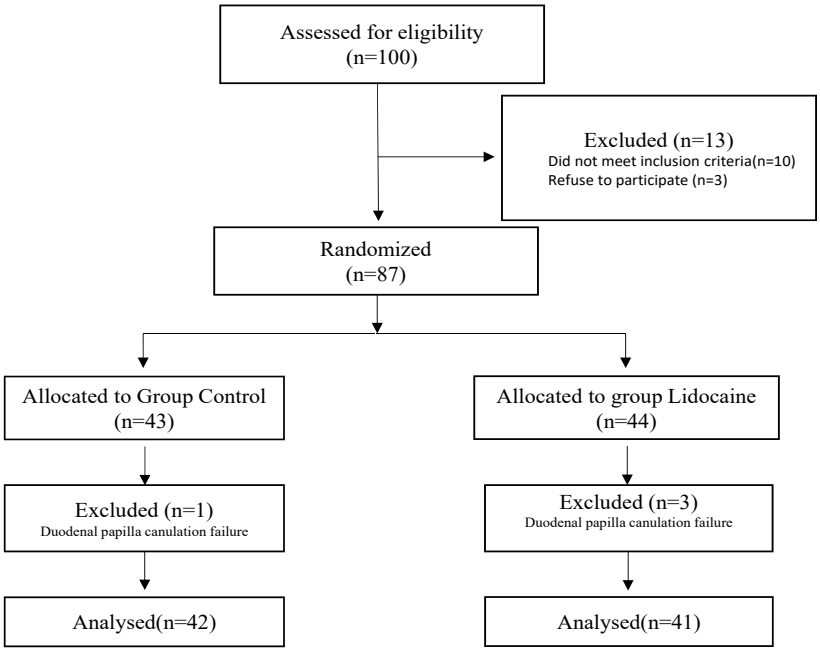

Fig. 1. Consort flow diagram.

Table I. Demographic characteristics of patients.

	Group L n=41	Group C n=42	p
Age, years	74.73 (±7.92)	72.62 (±5.88)	0.17
Gender, F/M	34/20	7/22	0.001
Weight, kg	72.85 (±14.28)	73.40 (±11.25)	0.84§
Height, cm	162 (±0.05)	165 (±0.05)	0.001§
BMI	27.59 (±5.23)	26.66 (±3.63)	0.35§
ASA II/III/IV	15/25/1	16/26/0	0.59
Comorbidities, n (%)			
Hypertension	40 (97.6)	35 (83.3)	0.02‡
Diabetes	11 (26.8)	13 (31.0)	0.67‡
Obesity	5 (12.2)	1 (2.4)	0.08‡
Indication for ERCP, n (%)			0.001‡
Bile duct stone	34 (82.9)	19 (45.2)	
Malignant obstruction	7 (17.1)	23 (54.8)	

Values are expressed as mean standard deviation or n (%); ‡ $\chi 2$ test; §Independent sample t test.

Table II. Outcomes

	Group L n=41	Group C n=42	p
Dose of propofol, mg	135.37 (±43.23)	214.88 (±51.83)	0.001
Awake time, min	2.85 (±1.50)	5.38 (±1.36)	0.001
Recovery time, min	6.32 (±2.58)	11.26 (±2.84)	0.001
Procedure time, min	23.90 (±12.66)	26.17 (±12.41)	0.41
Pain scores at 10 min, n (%)			0.13
VAS 0	34 (82.9)	39 (92.9)	
VAS 1	3 (7.3)	2 (4.8)	
VAS 2	4 (9.8)	0 (0)	
VAS 4	0 (0)	1 (2.4)	
Pain scores at 45 min, n (%)			0.54
VAS 0	38 (92.7)	39 (92.9)	
VAS 1	2 (4.9)	3 (7.1)	
VAS 2	1 (2.4)	0 (0)	

Values are expressed as mean standard deviation or n (%).

The consumption of propofol was statistically significantly lower in group L compared to group C (135.37±43.23 vs. 214.88±51.83, p<0.001). Also, the awakening time and the recovery time was statistically significantly lower in in group L compared to group C (p<0.001). We did not register significant differences in terms of the duration of the procedure, nor in terms of pain scores at 10 and 45 minutes, respectively, post-procedure (Table II).

In terms of complications, we recorded a desaturation rate below 94% higher in group C than in group L (33% vs. 0%, p<0.001), but no patients desaturated below 90%. In group L, the oropharyngeal reflex at the introduction of the duodenoscope was statistically significantly lower than in group C (p=0.003), as well as the periods of movement during the procedure (p=0.01) (Table III). The endoscopist's satisfaction was better in in group L compared to group C (p=0.006). No side effects due to the toxicity of i.v. administration of lidocaine were recorded.

DISCUSSION

In this study we evaluated the impact of i.v. lidocaine administration on the dose of propofol during the ERCP procedure in patients over 65 years of age. The study showed that the combination with lidocaine reduces the dose of propofol. This dose reduction of propofol has also been

Table III. Complications

	Group L n=41	Group C n=42	p
Desaturation			0.001
SaO_2 under 94%	0 (0%)	14 (33.3%)	
SaO_2 over 94%	41 (100%)	28 (66.7%)	
Oropharyngeal reflex			0.003
Absent	37 (90.2%)	26 (61.9%)	
Present	4 (9.8%)	16 (38.1%)	
Involuntary movement			0.001
Absent	31 (75.6%)	21 (50%)	
Present	10 (24.4%)	21 (50%)	
Lidocaine toxicity	0	0	N/A
Endoscopists satisfaction			0.006
Poor	0 (0%)	0 (0%)	
Moderate	0 (0%)	1 (2.4%)	
Good	2 (5.1%)	13 (31.0%)	
Excellent	37 (94.9%)	28 (66.7%)	

Values are expressed as mean standard deviation or n (%).

associated with a lower incidence of desaturation episodes and a faster wake-up and recovery time.

Lidocaine is a local anesthetic of the class of amides originally developed as an antiarrhythmic. Lately, it has been intravenously used for anti-inflammatory, analgesic properties, especially in abdominal surgery where it has been shown to reduce the need for opioids, reduce postoperative pain and decrease the duration of postoperative ileus. The analgetic effect of i.v. lidocaine occurs by reducing the nociceptor signal in the central nervous system by inhibiting the effects mediated by the G protein and by reducing the activity and sensitivity of neurons in the spinal cord [12-16].

However, we must not forget about the potential side effects that i.v. lidocaine administration may have. Studies have shown that plasma concentrations of lidocaine at which toxicity may occur are between 9–10 $\mu g.ml^{-1}$ and to avoid toxic effects the dose should be kept below 4 mg/kg/h [17]. Also, half-life of lidocaine was shown to be approximately 100 min following either a bolus or a continuous infusion lasting < 12 h [18]. The most common side effects associated with i.v. administration of lidocaine are those on the central nervous system (drowsiness, light-headedness, peri-oral numbness, tinnitus) and those on the cardiovascular system (bradycardia, myocardial depression, arrhythmias) but there have been described some less common side effects such as methemoglobinemia [19, 20]. Also, the side effects depend on the plasma concentration of lidocaine, which are even more severe as the plasma concentration is higher. The risk of lidocaine toxicity is also influenced by the patients' status, so severe liver or kidney dysfunction predisposes patients to the appearance of toxicity due to the reduction of clearance [21].

In this study, the dose of lidocaine used was well below the level of doses described to be toxic, and patients with severe liver or kidney dysfunction were excluded from the study. The effect of reducing the need for propofol by the association of i.v. lidocaine was reported by other authors. Foster et al [11] showed a 50% reduction in the dose of propofol by the association of lidocaine in lower digestive endoscopy procedures in adults, and Meizhen et al. [22] showed a 13.2% reduction in the dose of propofol in colonoscopy procedures in the pediatric population.

The ERCP procedure is instead more complex compared to lower digestive endoscopy. It is a painful, lengthy procedure that requires deep analgesia to avoid the movement of patients, which could lead to procedural complications. Also, patients with ERCP indication are generally elderly with associated comorbidities. Martindale et al. [1] reported that 46% of patients undergoing ERCP were ASA III–V, 89% percent of the patients in the study were ASA III, and 65% were above the age of 65. From this point of view, sedation may carry certain risks in these patients, risks related to the impact that propofol has on lung and cardiovascular function. Too deep a sedation can cause hemodynamic instability and respiratory failure manifested by hypotension and hypoxia and a superficial sedation can determine the intraprocedural movement of the patient with consequences on the procedural act.

The combination of lidocaine with propofol in our study determined the reduction of the dose of propofol by 37%. This reduction in the dose of propofol that we obtained is comparable to the data described by other authors. Ates et al. [23] reported a 32% reduction in the dose of propofol by adding lidocaine in ERCP procedures and in Liu et al. [24] study the reduction was 33.8%. The possible explanations for the differences between the previously reported values and our results would be the average age of the patients was higher by an average of 72 years, 61% of them being classified in the ASA III risk group.

Similar data with literature was obtained regarding the periods of intraprocedural movement of the patients and the oro-pharyngeal reflex at the introduction of the duodenoscope, these being statistically significantly lower in group L compared to group C [23].

In our study, the postprocedural pain did not differ between the two groups, similar to Ates et al. [18] findings but Liu et al. [24], detected a statistical difference in terms of the VAS scale with its reduction in the lidocaine group. This can be explained by the fact that different endoscopists performed the ERCP procedures in our study and their approach and experience could influence the pain scores. Also, the patients in our study had a higher average age than those in the study of Liu et al. [24], and the elderly have a lower pain threshold.

Li et al. [25] showed in his study that the association of lidocaine to propofol, in obese patients undergoing a colonoscopy, significantly reduced the number of episodes of desaturation and Chen et al. [26] showed that this association increased hemodynamic stability in elderly patients. In our study the incidence of hypoxia, defined as SpO_2<94% was significantly reduced in group L compared to group C, and in terms of hemodynamic stability even if the differences were not statistically significant, the patients in the group L had a more stable hemodynamics.

The satisfaction of the endoscopists was better in group L, as demonstrated by the other authors [23-24]. This satisfaction was related both to the periods of intraprocedural movement of the patients and to the time of awakening and recovery which

was statistically significantly lower in group L allowing a more efficient use of the endoscopy room.

Due to the relatively safe pharmacokinetic and pharmacodynamic profile, with certain precautions, lidocaine could be used as an adjunct by gastroenterologists in countries where legislation allows them to administer propofol for procedural sedation.

However, there are also some limitations of the study. First, the procedures were performed by several endoscopists, which could have influenced the time of carrying out the procedure and implicitly the consumption of propofol. But our hospital is a large volume center [27] with an average of 2000 ERCP/year; all the endoscopists are considered experienced and performed at least 300 therapeutic procedures/year for at least 5 years. It was documented that the adverse effects of ERCPs are related with the experience of the endoscopists [28]. Secondly, we did not use monitors to evaluate the depth of sedation such as Bispectral Index (BIS) or Narcotrend, so the evaluation of sedation was done through subjective observations. Thirdly, we did not determine the plasma concentration of lidocaine. Lidocaine was administered according to the Enhanced Recovery After Surgery (ERAS) 2016 recommendations, and we did not experience any side effects due to the toxicity of lidocaine.

CONCLUSIONS

The combination of lidocaine in elderly patients undergoing ERCP procedure significantly reduces the need for propofol, reduces periods of intraprocedural movement of patients with the increased satisfaction of endoscopists. Also, the reduction in propofol leads to a decreased incidence of desaturation and a better intraprocedural hemodynamics. Large, multicenter studies are required to confirm this effect and to develop analgesia guidelines in ERCP.

Conflicts of interest: None to declare.

Authors' contributions: C.B. conceived and designed the study. A.L.A. and O.U. collected and analyzed the data. V.M. and M.T performed the endoscopic procedures. C.B. drafted the manuscript. A.B., L.C. critically revised the work. D.I. supervised the study. All authors critically revised the manuscript, approved the final version to be published, and agree to be accountable for all aspects of the work.

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