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Sedations and Analgesia in Patients Undergoing Percutaneous Transhepatic Biliary Drainage

A. A. HATZIDAKIS*, E. CHARONITAKIS*, A. ATHANASIOU*, D. TSETIS*, G. CHLOUVERAKIS†, G. PAPAMASTORAKIS*, G. ROUSSOPOULOU*, N. C. GOURTSOYIANNIS*

**Department of Radiology, University Hospital of Heraklion, Medical School of Crete and †School of Education, University of Crete, Greece*

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AIM: To present our experience using intravenous sedoanalgesia for percutaneous biliary drainage.
MATERIALS AND METHODS: This study comprised 100 patients, all of whom were continuously monitored [electrocardiogram (ECG), blood pressure, pulse oxymetry] and received an initial dose of 2 mg midazolam followed by 0.02 mg fentanyl. Before every anticipated painful procedure, a maintenance dose of 0.01 mg fentanyl was administered. If the procedure continued and the patient became aware, another 1 mg midazolam was given. This was repeated if patients felt pain. A total dose of 0.08 mg fentanyl and 7 mg midazolam was never exceeded. Immediately after the procedure, the nurse was asked to evaluate patients' pain score. The patients were asked 3 h later to complete a visual 10-degree pain score scale.
RESULTS: The average dose of fentanyl and midazolam was 0.042 mg (0.03–0.08 mg) and 4.28 mg (2–7 mg), respectively. Only one patient recorded the procedure as painful. The scores given by the attending nurse (1–7 points, mean 2.9) correlated well with those given by the patients (1–6 points, mean 2.72). No complications were noted.
CONCLUSION: According to our experience, interventional radiologists practising biliary procedures can administer low doses of midazolam and minimize the doses of fentanyl, without loss of adequate sedation and analgesia. Hatzidakis, A. A. *et al*. (2003). *Clinical Radiology* **58**, 121–127.

Key words: interventional radiology, sedation, analgesia, iliary drainage, nursing care.

INTRODUCTION

Interventional radiological procedures have increased during the past decades in number, complexity and importance. They have been appreciated by clinicians and patients for their minimally invasive character and their use as a substitute for major surgical procedures. Nevertheless, the patient is awake during the majority of these interventions, thus making it important that the patient feels the least possible distress.

Major interventional procedures regarding discomfort and complication rates, include embolizations, renal and biliary drainage along with dilatations and transjugular intrahepatic portosystemic shunts (TIPSS) [1]. In many institutions, premedication has already been replaced by intravenous sedation and analgesia during these painful procedures [2]. Intravenous conscious sedation is a medically controlled state of depressed consciousness that allows the minimization of patient's anxiety and fear of pain, while muscle tension, blood pressure, heart and respiratory rates can be kept as normal as possible [3,4].

This can be achieved by using special protocols [2,5–8], most of which involve a combination of midazolam and fentanyl [5,8]. Currently, there is no accepted protocol that provides a safe and painless procedure without sedation-related complications. In this paper, we report our experience of intravenous sedation and analgesia during the performance of percutaneous transhepatic biliary drainage (PTBD).

MATERIAL AND METHODS

This prospective study was designed for two main reasons. First, in order to try to fractionate and minimize the doses needed for intravenous sedation and analgesia

Author for correspondence: Adam Hatzidakis, Em. Kastrinaki 7, 71306 Heraklion, Crete, Greece. E-mail: adamhatz@hotmail.com
Guarantor of study: Professor N. C. Gourtsoyiannis.

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during a major percutaneous intervention like PTBD, and second, to investigate whether these lower doses can still provide sufficient sedation and analgesia for the patients.

One hundred patients participated in the study, conducted during the last 3 years. The patients aged between 36–87 years (mean 68.7 years) with a mean weight of 65.1 kg (50–80 kg). Fifty-six were men (aged 36–83, mean 66.8) and 44 women (aged 49–87, mean 70.9). All patients were referred for PTBD because of malignant obstruction or benign disease. No metallic stenting was performed during these procedures. Twenty-three percent of the patients ($n = 23$) also suffered from other types of diseases besides biliary disease. Twelve had cardiac problems and six had liver disorders, while five suffered partial pulmonary insufficiency. Of the 23 patients, 11 also had diabetes mellitus and nine suffered renal function problems. No patient suffered dehydration or hypoalbuminaemia, conditions, which can increase the effect of the administered drugs. We excluded patients with non-correctable bleeding diathesis, extensive malignant or cystic liver disease, advanced renal and liver failure, and primary sclerosing cholangitis.

Solid food consumption was not allowed after midnight and clear fluid intake was restricted during the 4 h before the procedure. Each patient's coagulation profile was checked and corrected if possible. An intravenous line was secured and used for fluid and drug administration, along with other medication if necessary. Each patient's history, general condition and level of consciousness were studied. Patients provided written informed consent for sedation during drainage. The chairman of the ethics committee of our hospital indicated that approval was not required for this study, as this procedure was simply a standardization of existing practice in biliary interventions. No premedication was administered before the procedure and no anesthesiologists were present. A dedicated nurse, trained in monitoring, airway control, basic life support and resuscitation, was always present.

We used the opiate fentanyl (Fentanyl, Janssen-Cilag, Beerse, Belgium) and the benzodiazepine midazolam (Dormicum, Hoffmann-La Roche, Basel, Switzerland), which are widely used in combination for interventional radiological procedures. They provide a tranquil and drowsy effect on patients who are asleep but easily aroused and whose sensitivity to pain is reduced. If required, rapid recovery is achieved by administering the antagonist naloxone (Narcan, DuPont Pharma, Bad Homburg, Germany) for fentanyl (intravenous injection of 400 μg over 15 s) and flumazenil (Anexate, Hoffmann-La Roche, Basel, Switzerland) for midazolam (intravenous injection of 200 μg over 15 s).

Adverse respiratory effects may occur after administration of both drugs; fentanyl usually causes brachypnoea with long in- and expiration times (eurypnoea), while midazolam causes tachypnoea and shallow breathing. If the drug causing the adverse effect cannot be ascertained both antagonists can be administered.

The drugs were injected slowly and patients were monitored for 2–3 min to see how individuals responded in each case. All patients were continuously and meticulously monitored by non-invasive measurement of blood pressure and arterial oxygen saturation. Taking pulse and respiration rates as well as electrocardiographic monitoring is mandatory, according to the ASA (American Anaesthesiologic Association) rules for patients receiving intravenous sedoanalgetic drugs. During the procedure, a nurse monitored the patients, checked venous lines, recorded reactions and emotional status, and provided support. All measurable values were recorded in 5-min intervals during the procedure, and were noted on a special protocol sheet along with the drug doses administered.

Pre-oxygenation was performed on all patients for at least 5 min before the administration of drugs. This is a common used technique. A Venturi mask (28% O_2) or nasal prongs (4 l/min O_2) were used. This was continued, usually by means of a Venturi mask, throughout the whole interventional procedure and after until patients fully recovered. Based on pulse oxymeter interpretation, certain actions were carried out (Table 1).

The vast majority of the transhepatic punctures were performed through the right hepatic lobe. Along with intravenous sedoanalgesia, local anaesthesia was used on the site of puncture in form of lidocaine 2%. The local anaesthetic was injected subcutaneously up to the hepatic capsule. Emergency resuscitation equipment (including a defibrillator, supportive airway, ventilatory adjuncts and suction) and drugs were always available in the interventional room.

The sedation and analgesia protocol we used was the same for all patients, regardless of their age, sex, general condition and underlying disease. Two milligrams of midazolam and local skin anaesthesia were administered simultaneously. An injection of 0.02 mg fentanyl was administered 5–10 min later and always after midazolam onset. These were the loading doses used in all cases. We then noticed the lead time needed until the patient was ready. The sedative end point was determined by slurring of speech and ptosis (Verrill sign), at which time the actual procedure began. Before every anticipated painful procedure (e.g., insertion of a sheath, dilatation of the tract, expansion of the metallic stent), a maintenance dose of 0.01 mg fentanyl was given. We administered another dose of 1 mg midazolam if the patient was becoming conscious but the procedure had to be continued. We then waited the

Table 1 – Nurse actions in relation to oxygen saturation (after Skehan, *et al.*)

Oxygen saturation	Action
95–100	No further action
90–95	Order the patient to breath deeply
85–90	Interrupt procedure, assist ventilation (airway ± ambu bag)
<85 without improvement	Airway, ventilator bag, reversal agents, call an anaesthetist if saturation does not rise

prescribed time (lead time). The same was done if the patient felt pain. A total dose of 0.08 mg fentanyl and 7 mg midazolam was never exceeded.

After the procedure, the nurse attended the patient for at least 30 min (30–120 min, depending on the degree of consciousness), until the patient was fully awoken. Three hours later, all patients were asked to evaluate the degree of pain they felt during the procedure. A 10-degree pain score scale was showed to the patients, where 0 represented no pain and 10 was equivalent to the worst pain imaginable. The attending nurse was always surveyed before the patient was. All patients were kept in hospital overnight for observation.

Pain scores given by both the patient and the nurse were correlated. In each individual case, interprocedural blood pressure fluctuation, oxygen saturation, in addition to pulse and respiration rate, were calculated, and correlated with the patient's pain score and total drug dose, separately for midazolam and fentanyl. Pain was correlated with age, sex and total drug dose. Finally, procedure time was correlated with the patient's pain score, total drug dose, blood pressure and oxygen saturation.

Statistical analysis was performed using linear regression analysis and Pearson correlation. A p-value equal or less than 0.001 was considered statistically significant.

RESULTS

The procedure time ranged from 20–48 min (mean 31.1 min); fluoroscopy time was 7–21.3 min (mean 11.95 min). All procedures were successfully completed. Major complications were encountered in three cases; two subcapsular liver abscesses were separately and uneventfully drained. Another patient bled from the hepatic tract after catheter removal, and died, despite arterial embolization (procedure related mortality 1%).

The average dose of fentanyl administered was 0.042 mg (minimum 0.03 mg, maximum 0.08 mg) and that of midazolam was 4.28 mg (minimum 2 mg, maximum 7 mg). The largest dose of fentanyl (0.08 mg) combined with a large dose of midazolam (6 mg) was administered to a 65 year-old male patient who had already been on high doses of analgesics due to common bile duct cholangiocarcinoma. He also experienced the strongest pain recorded, and was the only patient to record the procedure as painful 3 days later. Apart from this case, the second largest fentanyl dose administered was 0.05 mg. No other patient reported a pain score higher than 5 points or remembered the procedure as painful. The scores given by the attending nurse (1–7 points, mean 2.9) significantly correlated to those given by the patients (1–6 points, mean 2.72) ($r = 0.897$, $p < 0.001$, Fig. 1).

The recorded pain score did not correlate with the patients' age ($r = -0.046$, $p = 0.653$), body weight ($r = 0.097$, $p = 0.337$), fluoroscopy time ($r = -0.048$, $p = 0.636$), whereas it marginally correlated with procedure time ($r = 0.167$, $p = 0.097$). Female patients experienced slightly more pain than male patients (mean 2.88 vs. 2.59, $p = 0.23$).

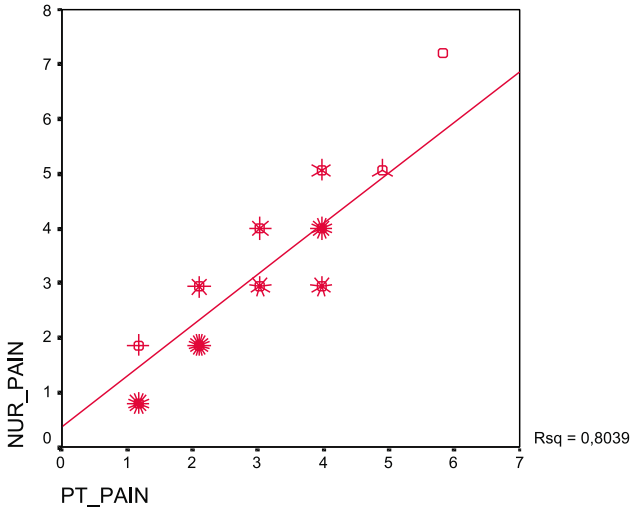

Fig. 1 – Correlation between pain score given by the patient and the nurse. NUR_PAIN, pain score given by the nurse; PT_PAIN, pain score given by the patient. One circle indicates 10 patients: Every ray on the circle stands for another one patient.

The pulse, respiratory rate and oxygen saturation were evaluated with regard to the difference between the initial and final number recorded. There was no significant change in the heart rate, respiration, arterial blood pressure and oxygen saturation values. Respiration was not depressed in any of the patients and there was no respiratory rate less than 12/min noticed. One patient (who reported feeling the most pain) experienced a respiratory rate varying between 28–36/min without oxygen saturation reduction lower than 92%.

Flumazenil was intravenously administered in four cases without inducing any consequences. In these four cases the procedure was relatively difficult and the patients were uncooperative, as a result larger doses of drugs were administered. We decided to wake them earlier than normal in order to assess their condition after the procedure. Delayed re-sedation is possible, so these patients were monitored closely for 3 h during recovery. However, antagonist administration for earlier recovery is generally not advocated.

The pain score provided by the patient did not correlate statistically with the interprocedural changes of the respiration rate ($r = 0.126$, $p = 0.211$), of the cardiac pulse rate ($r = -0.054$, $p = 0.59$), or oxygen saturation ($r = 0.203$, $p = 0.043$). There was also no correlation between pain score and the total dose of midazolam ($r = 0.049$, $p = 0.628$). Conversely, the relation of the pain score with the total dose of fentanyl (Fig. 2) was significant ($r = 0.458$, $p < 0.001$), especially for male patients (Fig. 3). The pain score also significantly correlated with the interprocedural blood pressure changes ($r = 0.424$, $p < 0.001$). The same was found between interprocedural blood pressure changes and the total dose of fentanyl ($r = 0.39$, $p < 0.001$) or midazolam ($r = 0.319$, $p = 0.001$).

No correlation was noted between interprocedural changes of oxygen saturation and the total doses of either fentanyl ($r = 0.09$, $p = 0.37$) or midazolam ($r = -0.168$, $p = 0.095$). The patient's age and weight did not correlate

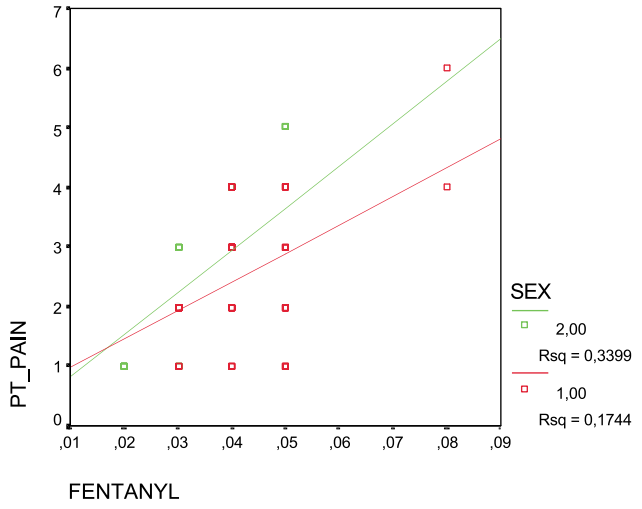

Fig. 2 – Correlation between pain score and fentanyl total doses. The red and green lines show the correlation between pain score and fentanyl total doses in male and female patients, respectively. It seems that female patients needed more fentanyl dose because of a relatively higher pain score. PT_PAIN, pain score given by the patient; Sex 1.00, males; Sex 2.00, females.

with any of the parameters. Finally, procedure time did not correlate with interprocedural changes of oxygen saturation ($r = -0.015$, $p = 0.88$) but it significantly correlated with interprocedural blood pressure changes ($r = 0.45$, $p < 0.001$).

DISCUSSION

Percutaneous transhepatic drainage for biliary decompression is a procedure of 20–60 min duration which requires a high level of sedation and analgesia. Procedures in the present study lasted 20–48 min (average 31 min), whereas the mean acceptable fluoroscopy time is 12 min.

Pain can occur at different stages of the procedure. Sedation and analgesia of the patient are mandatory. Intravenous conscious sedation is defined as a medically controlled state of depressed consciousness that (1) allows defensive reflexes to be maintained, (2) retains the patient's ability to preserve a patent airway independently and continuously, and (3) permits the patient's appropriate response to physical stimulation or verbal command [9]. So the patient's anxiety, fear of pain and actual pain itself can be controlled and minimized. In addition, the patient's heart and respiratory rates, blood pressure and muscle tension can be kept as normal as possible [3].

Midazolam is a synthetic imidazobenzodiazepine derivative, which can be used for sedation, having a prompt onset of action, usually after 2–3 min, and little cardiovascular or respiratory effect. In larger doses it may reduce blood pressure and produce respiratory depression. Significant reductions in oxygen saturation can be encountered during administration of midazolam, especially when it is injected in combination with other drugs, (e.g., in combination with pethidine). Pulse oximetry is a useful monitor for detection of hypoxia in such cases [10]. Its half-life is 1–4 h, but this may be significantly prolonged in elderly patients or in cases of patient's with liver failure [8,11]. It provides sedation by decreasing the level of consciousness but does not reduce pain. It has an excellent anxiolytic effect and causes retrograde amnesia and less postprocedural drowsiness than diazepam [8].

Fentanyl is a potent, synthetic opioid narcotic having a rapid onset between 3–10 min; it has a shorter duration of action than morphine and provides comfort and good

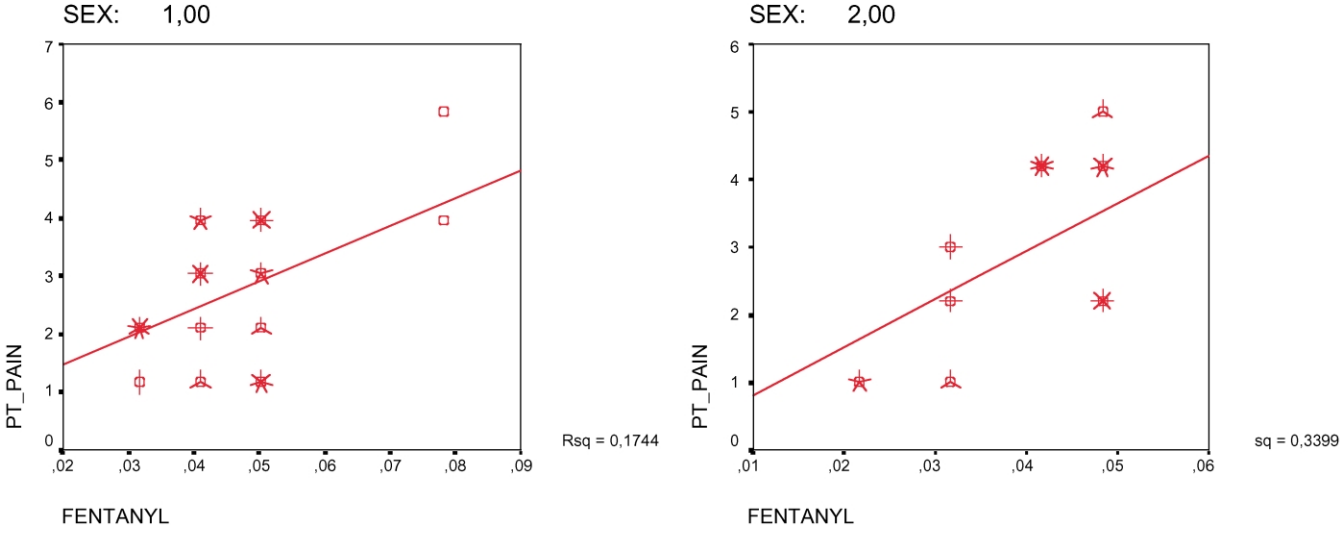

Fig. 3 – Correlation between pain score and fentanyl total doses in relation to patient's sex. In this table, we can see the pain score given by the male (left) and female (right) patients in relation to the total fentanyl dose administered. The markers on the graphics give the number of the patients for each pain score. (One circle on the graph stands for 10 patients. Every ray on the circle stands for another one patient.) PT_PAIN, pain score given by the patient; Sex 1.00, males; Sex 2.00, females.

analgesic effects. It is metabolized in the liver and excreted in the urine. It produces a potent analgesic effect with few cardiovascular disorders, but in higher doses it may induce respiratory depression and spontaneous respiration block [8,12].

Midazolam and fentanyl is a potent combination, which can cause hypoxia or even respiratory arrest, especially in patients with respiratory syndromes, and elderly, fragile or neurological patients. There is often great variability in the so-called effective doses among individuals. So the inter-patient variability in response to the drugs can vary enormously and patient response is not predictable. They are a better alternative to pethidine and diazepam because they can be more tightly titrated and controlled, and are safer and more suitable for use in outpatients [13].

There are several interventional radiological studies, using special protocols of different drug combinations Table 2 [2,5–8,14]. Most of these use a combination of midazolam and fentanyl [5,8,14,15], which has been proved to be safe and efficient [2,14]. Midazolam versus propofol has been also studied [7]. A comparison of intravenous sedation with either epidural anaesthesia [16], or with coeliac plexus block [17] or with other combinations [13] are also reported.

Not all interventional radiologists are familiar with sedation and analgesia during biliary or other kind of percutaneous procedures. British and Irish interventional radiologists always use sedation in 66% of biliary procedures and occasionally in 18% [18], while Belgian radiologists practise conscious sedation in 53% of such cases [19]. An asleep–arousable condition or deep sedation is more frequently used in USA than in Europe for the same kind of procedures [1,20]. General anaesthesia is used in less than 8% of the cases. In general, it is a trend in Europe to use less sedoanalgesia than in the United States [20]. In the United States, midazolam is the most popular drug in 92% of the cases and fentanyl in 62% In comparison, Europeans use midazolam and fentanyl in only 58 and 33% of the cases, respectively [20]. It is not clear whether this is due to the lack in number of trained nursing staff or fear of using sedation, especially fentanyl. Of course, it would be better to perform such procedures in the presence of an anaesthetist, but this is seldom practical in most hospitals.

Fentanyl and midazolam may be the ideal drugs for use in interventional radiological procedures because they have rapid clearance rates and short elimination half-lives. As they act synergistically, it is better to administer them separately [8]. There are protocols using this drug combination [2,5,6,8]. Cragg used a loading dose of 0.145 mg/kg midazolam combined with a fentanyl loading dose of 0.00725 mg/kg (maintenance doses for both drugs were half the initial dose) [2]. This represents 1.0 mg midazolam and 0.05 mg fentanyl as loading doses for a patient weighting 70 kg. He used this for lower extremity angiography on fully monitored patients and administration of 3 l/min O_2. Mueller used 1–4 mg midazolam and 0.05–0.2 mg fentanyl as loading doses for a 70 kg patient and half of each as a maintenance dose administered every 5 min for low and high-grade pain procedures. He estimated these doses according to the severity of the procedure [5]. Manninen used 1 mg midazolam as a bolus, followed by an infusion of 0.3 mg for a 70 kg patient, combined with 0.05 mg fentanyl. He correlated this combination with that of midazolam and propofol and found no significant difference between them [6]. Skehan *et al*. [8], used a five-step protocol for every kind of interventional procedure. They first injected 0.001 mg/kg fentanyl followed by 0.01–0.035 mg/kg midazolam. The midazolam dose was determined based on the age and general condition of the patient. The maintenance doses were equal to the loading ones. In 97% of the cases the patients needed one loading and one maintenance dose from each drug for the whole procedure. Patients undergoing more complex procedures (55%) received supplemental O_2 from the beginning. We also recommend patient pre-oxygenation. Savader *et al*. [17] used an infusion pump for drug administration during percutaneous biliary drainage, injecting 0.2 mg midazolam and 0.0025 mg fentanyl every 3 min. A mean dose of 2.0 mg midazolam and 0.0247 mg fentanyl was used in the control placebo group without coeliac plexus block. These

Table 2 – Sedation and analgesia protocols

	Midazolam loading maintenance doses		Fentanyl loading maintenance doses		Type of intervention
	loading doses	maintenance doses	loading doses	maintenance doses	
Cragg *et al*. [2] for 70 kg pt	1 mg	0.5 mg	0.05 mg	0.025 mg	Lower extremities angiography
Mueller *et al*. [5] for 70 kg pt	1 mg	0.5 mg	0.05 mg	0.025 mg	Biopsy
	3–4 mg	1.5–2 mg	0.1–0.2 mg	0.05–0.1 mg	Biliary drainage
Manninen *et al*. [6] for 70 kg pt	1 mg	0.3 mg infusion	0.05 mg	–	Neuroradiology procedures
Skehan *et al*. [8] for 70 kg pt	0.7–2.45 mg	0.7–2.45 mg	0.07 mg	0.07 mg	All kind of procedures
Mean doses for 70 kg pt	2.7 mg (range 0.5–9.5)		0.143 mg (range 0.05–0.4)		All kind of procedures
Our protocol for every pt	2 mg	1 mg	0.02 mg	0.01 mg	Biliary drainage
Mean doses for 65 kg pt	4.28 (range 3–7)		0.042 mg (range 0.02–0.08)		

Abbreviations: mg, milligram; kg, kilogram; pt, patient.

are the lowest previously reported doses to date, where a very satisfactory pain score of 2.1 was noticed. Arepally *et al*. [14] reported an average midazolam dose of 4 mg and an average fentanyl dose of 0.16 mg. They did not mention initial doses used for biliary interventions, but stated doses of 0.5–2 mg midazolam and 0.025–0.05 mg fentanyl for various interventional procedures. They also used the highest dose levels for biliary interventions. Until now, there is no accepted protocol that provides a safe and painless procedure without sedation-related complications. In the present study we used a mean total dose of 4.28 mg midazolam and 0.042 mg fentanyl for a mean patient weight of 65 kg. This is less than the doses recently reported for the same kinds of procedures [1,14–17]. This indicates that our protocol may be more efficient than previously published studies, and is recommended for use during biliary procedures. Nevertheless, no definitive conclusion can be made without a randomized study of different protocols during percutaneous transhepatic procedures.

Severe complications of conscious sedation are rare. Exacerbation of congestive heart failure, episodes of coughing, respiratory depression are reported [2,7]. We did not encounter any cases with a saturation decrease below 90%, perhaps because of the supplemental oxygenation we used in every case. We also did not note any other kind of complications, even after administering the highest doses.

The correlative significance between the pain score and the total dose of fentanyl is explained by the fact that when the patient felt more pain, more fentanyl was injected. The administered drug doses are independent of each patient's age, sex, weight, disease or general condition, and allows low-dose sedation and analgesia during biliary drainage.

The only significant correlations found were those of interprocedural blood pressure with pain score, and procedure time with total doses of fentanyl and midazolam. Usually, it is the interprocedural oxygen saturation that correlates with these parameters, but this was not the case in the present study. Blood pressure changes were monitored frequently, but did not lead to any complications during our study.

About 83–87% of interventional radiology teams use dedicated full-time nurses [1,20]. Pre-procedural assessment of a patient's general condition, intake of medication, level of consciousness is also important [3,21]. Correct patient monitoring, using ECG, pulse oximetry, blood pressure measurement, and supplemental oxygenation throughout the procedure, can reduce the chances of hypoxia occuring [8,22]. The nurse has to monitor the patient's condition, be aware of any complications, be trained for emergency resuscitation, and properly calculate the drug doses [21]. Special interprocedural care includes observing and supporting patients emotionally and acting as an advocate and a contact between patient and physician [4,23].

During the biliary procedures undertaken in the present study initial doses of midazolam and fentanyl were administered, followed by fragmented maintenance doses according to patients' discomfort and anticipated pain. This enabled us to keep the drug total doses to a very low level, especially for fentanyl, without loss of adequate analgesia and with no apparent adverse effects. We conclude that our protocol, using relative lower doses of drugs, can provide sufficient sedation and analgesia during major percutaneous interventions like PTBD.

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