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Pharmacology in Emergency Medicine

Procedural Sedation With Dexmedetomidine in Combination With Ketamine in the Emergency Department

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□ **Abstract—Background: Dexmedetomidine is an alternative agent for procedural sedation in the emergency department thanks to its ability to maintain hemodynamic and respiratory stability. Dexmedetomidine must, however, be combined with a powerful analgesic. Objective: Our aim was to evaluate the quality and safety of procedural sedation using the combination of dexmedetomidine and ketamine for patients undergoing painful procedures in the emergency department. Methods: This prospective interventional single-center study was conducted in an academic emergency department of an urban hospital in Brussels, Belgium. Patients received a bolus injection of 1 μg/kg dexmedetomidine over 10 min and then a continuous infusion of 0.6 μg/kg/h followed by a bolus of 1 mg/kg ketamine. The painful procedure was carried out 1 min later. The level of pain was evaluated with a numerical rating scale from 0 (no pain) to 10 (maximal pain). The level of patient comfort for the procedure was measured using a comfort scale. Results: Thirty patients were included. Overall, 90% of patients felt little or no pain (n = 29 of 30) or discomfort (n = 28 of 30) during the procedure. One patient experienced apnea with desaturation, which was resolved by a jaw-thrust maneuver. Although 23% of patients had significant arterial hypertension, none required drug treatment. Conclusions: The combination of dexmedetomidine and ketamine provides conscious sedation, bringing comfort and pain relief to patients in optimal conditions for respiratory and hemodynamic safety. However, sedation and recovery times are longer than with conventional drug combinations. The dexmedetomidine–ketamine combination should therefore be recommended for nonurgent procedures and fragile patients.**

□ **Keywords—Procedural sedation; Emergency department; Dexmedetomidine; Ketamine**

Introduction

Procedural sedation for patients undergoing painful procedures has become a daily occurrence in emergency departments. For this purpose, it is essential to use sedatives that ensure the best hemodynamic and respiratory stability. Moreover, emergency department patients are rarely fasting and are frequently of advanced age, which is a morbidity factor during sedation. Furthermore, medical history is often poorly documented. The drugs used for procedural sedation should thus provide sufficient pain relief and rapid recovery. Propofol is a sedative agent that has been used for procedural sedation in emergency departments since 1996 (1). Propofol is effective in adults, but it often has a very narrow therapeutic window and the dose is unpredictable (2). In addition, apnea occurs in more than one-half of the patients, although not evolving to hypoxia (1–12% of cases) (3). The other most common

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adverse effect using propofol is hypotension (4–17% of cases) (4).

Serious respiratory events, such as laryngospasm, are rare (< 1% of sedations).

Dexmedetomidine may be an interesting alternative to propofol (5–7). Dexmedetomidine is a highly specific $\alpha 2$ adrenergic receptor agonist with linear pharmacokinetic characteristics, a half-life of 6 min, and an elimination half-life of 2–3 h. The mild sedative effect of dexmedetomidine is similar to physiological sleep. With therapeutic plasma concentrations, minimal respiratory depression is seen, with a preservation of ventilatory response to CO_2 (8).

As dexmedetomidine has only modest analgesic effects, it is preferable to combine it with an analgesic, such as an opioid. In a 2018 study, the combination of dexmedetomidine and remifentanil was compared with that of midazolam and remifentanil (9). This study demonstrated that dexmedetomidine–remifentanil was more effective and safer than midazolam–remifentanil.

Ketamine is an N-methyl-D-aspartate receptor antagonist that provides sedation, analgesia, and amnesia without causing respiratory depression (10). Ketamine has a positive inotropic action and vasoconstriction that produces increases in blood pressure and pulse rate. It was assumed that the combination of ketamine with dexmedetomidine would maintain optimal hemodynamic stability due to their antagonistic effects on heart rate (HR) and blood pressure. Ketamine use alone for procedural sedation is associated with a risk of unpleasant recovery reactions (e.g., anxiety, nightmares, agitation, confusion, and hallucinations). Ketamine causes hypersialorrhea (11). Furthermore, the properties of dexmedetomidine can reduce the unpleasant recovery reactions and hypersalivation associated with ketamine use.

The dexmedetomidine–ketamine combination has been studied especially for procedural sedation in children. A review from 2012 concluded that this combination was effective in most studies, but with a longer sedation time compared with conventional sedatives (12). To our knowledge, only one study to date has been conducted in adults. This 2016 pilot study on 24 patients investigated dexmedetomidine–ketamine for procedural sedation in an emergency department (13). The authors observed a low rate of adverse respiratory events and hypotension. No case of bradycardia was reported. The injection methods nevertheless differed from those proposed in the present study.

The main objective of the present study was to evaluate the quality and safety of procedural sedation using the combination of dexmedetomidine and ketamine for patients undergoing painful procedures in the emergency department. The secondary objective was to evaluate how dexmedetomidine reduces ketamine-induced dissociative symptoms and prevents the hypersalivation sometimes caused by ketamine sedation (14).

Materials and Methods

Study Design

This feasibility single-center study was conducted in an academic emergency department of an urban hospital in Brussels, Belgium. This study used a convenience sample of 30 patients.

The study was approved by the ethics committee of the Cliniques Universitaires Saint-Luc (2014/13NOV/551) and the Federal Agency for Medicines and Health Products (EudraCT Number: 2014-005170-11).

Population Description

All patients older than 18 years and requiring procedural sedation in the emergency department were eligible for inclusion. In accordance with expert recommendations, procedural sedation was indicated for the following conditions: fracture or dislocation reduction, abscess incision, and chest tube insertion. Exclusion criteria were refusal to participate in the study, unable to provide consent, pregnancy, hypotension or hypertension (systolic blood pressure [SBP] $\leq$ 100 mm Hg or $\geq$ 180 mm Hg), tachycardia or bradycardia (HR > 120 beats/min or < 50 beats/min), polypnea or desaturation (respiratory rate > 30 breaths/min or SpO_2 < 90%), and contraindication to dexmedetomidine or ketamine use.

Intervention

During the entire sedation, patients were continuously monitored for cardiovascular (HR and blood pressure) and respiratory (oxygen saturation and CO_2 concentration) functions. An electrocardiogram was recorded before and after sedation.

The American Society of Anesthesiologists (ASA) physical status classification score was used to determine patient's pre-sedation status.

At time 0, patients received a bolus injection of 1 μg/kg dexmedetomidine over 10 min. Patients 65 years and older received a half-dose. After the bolus dose, patients were given a continuous infusion of 0.6 μg/kg/h dexmedetomidine (15). The time to achieve conscious sedation, corresponding to a Ramsay Sedation Scale (RSS) score of 2 or 3, was calculated from the start of dexmedetomidine administration. RSS was measured by the investigator.

After reaching the desired level of sedation with dexmedetomidine, patients received an i.v. dose of 1 mg/kg ketamine. Older adult patients 75 years and older

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received a dose of 0.5 mg/kg ketamine (16). The procedure was performed 1 min after the injection of ketamine. If patients felt any pain during the procedure, a second dose of 0.5 mg/kg ketamine was administered.

The duration of the following three phases of the sedation were measured: 1) the sedation time, corresponding to the duration between the initial dexmedetomidine injection and the achievement of moderate sedation in which the patient is loaded with dexmedetomidine, 2) the procedure time, and 3) the emergence time was the time required to return to pretreatment level of verbalization and awareness.

We determined that the combination of dexmedetomidine and ketamine was safe if the patient had no respiratory or hemodynamic adverse events. Respiratory adverse events were defined as oxygen desaturation (SpO_2 $< 90\%$) or central apnea > 20 s. Hemodynamic adverse events were defined as hypotension (SBP ≤ 100 mm Hg), bradycardia (HR < 50 beats/min), or dysrhythmia.

The quality of the combination was determined based on the absence of unpleasant recovery reactions, pain, or discomfort.

The investigator in charge of the procedure reported any agitation during or after the procedure, and the patients were asked about any unpleasant recovery reactions after reaching the emergence time. An unpleasant recovery reaction was defined as agitation, unpleasant dreams, or unpleasant hallucinations. During sedation, the pain was subjectively evaluated by the investigator because the patient could not communicate (dexmedetomidine has amnestic effects and ketamine is dissociative). If the patient presented any sign of pain (e.g., wincing, frowning, and crying), an additional bolus of ketamine (0.5 mg/kg) was administered.

After sedation, patients were asked to rate their pain perception during the procedure using a numerical rating scale (NRS) from 0 (no pain) to 10 (maximal pain).

During the procedure, patient comfort was evaluated using a comfort scale. As pain intensity was difficult to accurately assess, the use of a comfort scale seemed more realistic for patients. A comfort scale allows a global assessment that takes into account the patients' environment. Some patients not only reported discomfort due to the pain itself but also secondary discomfort due to the room temperature, alarm noises, or stretchers. Patient comfort was evaluated using an NRS. After the procedure, the patients were asked to choose from 0 (very comfortable) to 10 (very uncomfortable).

We considered the patient to have hypersalivation after the ketamine injection if the physician had to aspirate the patient's saliva during the procedure. We asked the patient whether they had a dry mouth (yes or no) after the sedation. Dry mouth was not considered an unpleasant event.

Table 1. Frequency of Procedures Performed Under Sedation.

Procedure	n	%
Wrist fracture reduction	14	47
Ankle fracture reduction	3	10
Shoulder dislocation reduction	7	23
Elbow dislocation reduction	2	7
Chest tube insertion	2	7
Fifth metacarpal fracture reduction	1	3
Fecal impaction removal	1	3
Total	30	100

The physicians who performed the procedure were asked to evaluate the muscle relaxation of patients and the ease of performing the procedure with the sedative combination. The physicians who performed the procedure were an emergency physician or orthopedist.

Statistical Analysis

Quantitative variables were presented as mean and standard deviation or median and minimum and maximum. Qualitative variables were presented as frequency and percentage per category. Statistical analyses were performed using REM software, version 2.0 (REM Inc.).

Results

The study included 30 patients over a period of 6 months. The patients were mostly women (63.3%) and mean age was 58 years (range 22–95 years). Most patients (n = 19 of 30) had an ASA score of 1, seven patients had an ASA score of 2, and 2 patients had an ASA score of 3.

The most common procedures were Colles' fracture reduction and shoulder dislocation reduction. The different conditions requiring procedural sedation are summarized in Table 1.

The durations of the three sedation phases are presented in Table 2.

All patients reached a level of conscious sedation after injection of dexmedetomidine. After administration of ketamine, all patients entered a state of deep sedation equivalent to an RSS score of 4 or 5. No patient reached a level of sedation equivalent to RSS score of 6.

During sedation, one case of apnea with desaturation was observed, which was resolved by a jaw-thrust maneuver. There were no other respiratory complication.

In terms of hemodynamics, 23% of patients (n = 7 of 30) presented significant arterial hypertension (SBP $>$ 180 mm Hg) after ketamine administration, although none

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Table 2. Duration of the Different Phases from Sedation to Recovery of Consciousness.

Variable	Median	Minimum	Maximum	Standard Deviation
Sedation time, min	13.50	10	22	2.869
Procedure time, min	9.50	1	21	5.449
Emergence time, min	21.50	3	38	9.810

Table 3. Results of the Pain and the Comfort Scales.

NRS	0	Light (1–3)	Moderate (4–6)	High (7–10)	Total
Pain*	27	2	0	1	30
Comfort†	24	4	2	0	30

NRS = numerical rating scale.
* 0 (no pain) to 10 (maximal pain)
† 0 (very comfortable) to 10 (very uncomfortable).

required drug treatment. No cases of hypotension, dysrhythmia, or atrioventricular block occurred during the sedation.

Most patients (n = 26 of 30; 86.5%) had no hemodynamic, respiratory, or digestive complications during the recovery phase.

After the procedure, 1 patient experienced transient arterial hypotension and another patient had orthostatic symptoms when standing up. Finally, 2 patients had transient vertigo and vomiting during the recovery phase. All patients experienced dry mouth on awakening. Most patients (n = 24 of 30) felt no discomfort during the procedure, 4 patients had slight discomfort (rated as 2 or 3 out of 10), and 2 patients had moderate discomfort (rated as 5 or 6 out of 10). Most patients (n = 27 of 30) reported no pain (rated as 0 out of 10) during the procedure, 2 patients had a slight pain (rated as 2 or 3 out of 10), and 1 patient reported a high level of pain (rated as 8 out of 10) Table 3. present the results of the pain and the comfort scales**.**

Of the 30 patients, 7 needed an additional bolus of ketamine. Although possible according to our protocol, no third bolus was administered during the procedure. Interestingly, among the 7 patients who required a second bolus, none reported pain during the procedure (pain rated 0 out of 10 for the 7 patients). Ninety percent of patients felt little or no discomfort.

Most of the patients (n = 28 of 30) expressed their desire to be sedated with the same medications in the future.

Table 4 summarizes the occurrence of ketamine-induced recovery reaction. We differentiated the symptoms reported as pleasant by patients from those experienced as unpleasant.

All of the procedures could be completed in the emergency department. Overall, 60% of physicians considered that the procedure was easier to perform with the dexmedetomidine compared with conventionally used sedative molecules, and the remaining physicians did not report any difference. Excellent or good muscle relaxation was reported in 80% of cases.

Table 4. Frequency of Dissociative Symptoms Associated with Ketamine Use.

Dissociative Symptoms	n	%
None	8	27
Agitation	3	10
Minimal emergence phenomena*	2	7
Substantial emergence phenomena†	0	0
Pleasant dream	12	40
Unpleasant dream	1	3
Not communicated	4	13
Total	30	100

* Calm or pleasant auditory or visual illusions.
† Unpleasant hallucination.

Discussion

This feasibility study of 30 patients undergoing procedural sedation in our emergency department suggests that the combination of dexmedetomidine and ketamine provides effective and safe sedation. Indeed, all patients achieved the desired level of sedation. All of the procedures could be completed in the emergency department. During the procedures, all patients had optimal hemodynamic and respiratory stability.

In terms of respiratory complications, 1 patient (1 of 30 [3.33%]; 95% confidence interval [CI] 0.08–17.22%)

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experienced apnea with desaturation, which was rapidly resolved with a simple maneuver. These results seems better than those observed in the literature for propofol alone or a propofol–ketamine combination (respiratory adverse effects in 20–50% of patients) (3,17,18). In terms of hemodynamic parameters, almost one-quarter of patients presented a hypertensive peak that rapidly and spontaneously resolved. No patients (0 of 30 [0%]; 95% CI 0–11.6%) experienced hypotension or dysrhythmia during the sedation period.

The present study investigated whether the dexmedetomidine–ketamine combination provided patients with pain relief and maximum comfort during the procedure. Our findings appear to confirm this objective because most of the patients expressed their desire to be sedated with the same medications in the future. One of the main sources of discomfort with ketamine sedation related to the occurrence of unpleasant recovery reactions and agitation that can be distressing for both patients and health care professionals. We hypothesized that dexmedetomidine would limit these effects. In our study, most patients (46.7%) reported minor or pleasant symptoms or no psychoactive effects (26.7%) during ketamine administration. Four patients (4 of 30 [13%]; 95% CI 3.8–30.7%) experienced agitation or unpleasant dreams. It is difficult to compare our results with studies evaluating unpleasant recovery reaction with ketamine during procedural sedation in the ED. Indeed, no agreement on the definition could be found in the available literature. In addition, the methods for measuring these reactions vary among groups of researchers. For classical associations with ketamine (propofol and midazolam), reported results in the literature seem similar to our findings. A 2016 review and meta-analysis found that the prevalence of recovery reaction was lower with the combination of ketamine and propofol (ketofol) (48.1 per 1000 sedation; 95% CI 12.9–83.3) than with ketamine alone (164.1 per 1000 sedation; 95% CI 94.8–233.5) (19). This observation has since been confirmed by a study that focused on the frequency and severity of unpleasant recovery reactions between ketamine alone and ketofol (22.3% for ketofol vs. 44.7% for ketamine alone; difference 22.4%; 95% CI 7.4–36.1%) (20). Unpleasant recovery reactions were less common when the patients received midazolam prophylaxis (8% vs. 25%; difference 17%; 95% CI 6–28%) (21). This benefit was confirmed in a second study in 2018 (26.2% ketamine alone vs. 5% ketamine with midazolam; difference 21.2%) (22).

Another adverse effect of ketamine sedation is hypersialorrhea, and dexmedetomidine causes dry mouth. In our study, all patients reported dry mouth on awakening.

A major limitation of sedation in emergency departments is the requirement for a rapid onset of sedation and a short duration of action. In our study, the time taken to reach the desired level of sedation with the dexmedetomidine–ketamine combination was relatively long (median 13.5 min; range 10–22 min) compared with propofol (mean ± standard deviation 2.1 ± 1.2 min) or ketamine alone (30 s) (23). In light of these findings, it appears that our combination is not favorable in situations requiring a rapid intervention, such as an ankle dislocation with perfusion problems.

Finally, the time required to regain consciousness is longer with the dexmedetomidine–ketamine combination (median 21.5 min; range 3–38 min) than with propofol alone (median 5 min), ketamine alone (median 14 min; range 2–47 min), or propofol–ketamine (median 8 min) (24,25).

Limitations

The main limitation of this study was the small sample size, limiting the inference of the results. As this work was a feasibility study, no sample size could be calculated due to lack of previous evidence. As our sample is small (n = 30), we had wide CIs. In this study, it is reasonable to suspect bias due to the nonblinded patients and investigators.

The administered dose of 1 mg/kg ketamine is the dosage recommended by the guidelines for procedural sedation in adults when ketamine is the main sedating agent (26). Consequently, it is not possible to determine whether the effectiveness of sedation was due to the dexmedetomidine–ketamine combination or ketamine alone. It would be interesting to undertake another study with lower doses of ketamine (0.5 mg/kg). This dose is classically used when ketamine is combined with propofol for procedural sedation (27). Finally, we evaluated different painful procedures, such as fracture reduction, dislocation reduction, and chest tube insertion, with a single scale and the same drug doses. The pain levels and required sedation of each of these procedures are nevertheless likely to differ from each other.

Conclusions

Our study suggests that the combination of dexmedetomidine with ketamine can achieve deep sedation with optimal respiratory and hemodynamic stability. In addition, dexmedetomidine–ketamine seems to provide excellent comfort and pain relief to most of the treated patients. Nevertheless, the time required to obtain the desired level of sedation, as well as the recovery time, are much longer than those observed with conventional drugs. For this reason, the dexmedetomidine–ketamine combination may be preferable for fragile patients who require strict hemodynamic and respiratory stability.

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ARTICLE SUMMARY

1. Why is this topic important?

Procedural sedation for patients undergoing painful procedures has become a daily occurrence in emergency departments. For this purpose, it is essential to use sedatives that ensure the best hemodynamic and respiratory stability.

2. What does this study attempt to show?

This study attempts to show the quality and safety of procedural sedation using the combination of dexmedetomidine and ketamine for patients undergoing painful procedures in the emergency department.

3. What are the key findings?

The combination of dexmedetomidine and ketamine provides conscious sedation, bringing comfort and pain relief to patients in optimal conditions for respiratory and hemodynamic safety. However, sedation and recovery times are longer than with conventional drug combinations.

4. How is patient care impacted?

The dexmedetomidine–ketamine combination can be interesting for fragile patients who require strict hemodynamic and respiratory stability during procedural sedation.

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