American Journal of Emergency Medicine xxx (2018) xxx–xxx

Contents lists available at ScienceDirect

American Journal of Emergency Medicine

journal homepage: www.elsevier.com/locate/ajem

Comparison of the combination of propofol–fentanyl with combination of propofol–ketamine for procedural sedation and analgesia in patients with trauma

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ARTICLE INFO

Article history:
Received 30 September 2017
Received in revised form 24 January 2018
Accepted 25 January 2018
Available online xxxx

Keywords:
Procedural sedation and analgesia
Emergency department
Propofol
Fentanyl
Ketamine

ABSTRACT

Objective: Many procedures performed in emergency department are stressful and painful, and creating proper and timely analgesia and early and effective assessment are the challenges in this department. This study has been conducted in order to compare the efficacy of propofol and fentanyl combination with propofol and ketamine combination for procedural sedation and analgesia (PSA) in trauma patients in the emergency department.
Method: This is a randomized prospective double-blind clinical trial conducted in the emergency department of Imam Khomeini Hospital, a tertiary academic trauma center in northern Iran. Patients with trauma presenting to the emergency department who needed PSA were included in study. Patients were divided into two groups of propofol fentanyl (PF) and propofol ketamine (PK). Pain score and sedation depth were set as primary outcome measures and were recorded.
Results: Out of about 379 patients with trauma, who needed PSA, 253 met the criteria to be included in the study, 117 of which were excluded. The remaining 136 patients were randomly allocated to either PF group (n = 70) or PK group (n = 66). Pain management after drug administration was significantly different between the groups and the analgesia caused by fentanyl was significantly higher than ketamine. The sedation score after 15 min of PSA in the group PF was significantly higher than the group PK.
Conclusion: It seems that regarding PSA in the emergency department, PF caused better analgesia and deeper sedation and it is recommended to use PF for PSA in the emergency departments.

1. Introduction

Pain is one of the most prevalent clinical complaints for which patients refer to emergency departments and creating proper and timely analgesia and early and effective assessment are the challenges in this department [1]. Trauma is also one of the most common causes of patients' referral to the emergency departments, and many patients with fractures, dislocations and lacerations refer to emergency departments [2]. Many procedures performed in emergency departments are stressful and painful including restoration of fractures and dislocations, laceration repair, bone marrow aspiration, abscess drainage, central venous catheter insertion, etc. [2,3]. Procedural sedation and analgesia (PSA) is an important aspect of the skills of emergency medicine specialists [4]. PSA refers to using sedative drugs with or without analgesic drugs for doing a stressful and painful procedure while maintaining cardiovascular and respiratory functions [5]. Various medications such as propofol, benzodiazepines like midazolam, opiates like fentanyl and etomidate are used in the emergency department for PSA, each of which has its own advantages and disadvantages [6]. The guideline published by Difficult Airway Society (DAS) in 2015 suggested that using ketamine with midazolam or propofol is beneficial and effective in short procedures for trauma patients in ICU [7], but Emergency Medicine physicians most often use a combination of midazolam and fentanyl for PSA and do not usually use new medications like propofol and ketamine [8]. Since propofol has not been shown to have an analgesic effect, it was used in combination with fentanyl and to prevent induction of dyspareunia and hallucination by ketamine, it was used in conjunction with propofol. Therefore, this study has been conducted in order to compare the efficacy of propofol and fentanyl combination with propofol and ketamine combination for PSA in trauma patients referred to the emergency department.

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https://doi.org/10.1016/j.ajem.2018.01.080
0735-6757/

2. Methods and materials

2.1. Study design and centre

This is a randomized prospective double-blind clinical trial conducted in the emergency department of Imam Khomeini Hospital, a tertiary academic trauma center in northern Iran, which sees about 90,000 patients annually in cooperation with Mazandaran Orthopedic Research Center. This research was conducted from June 2016 to April 2017. It was approved by the Ethics Committee of Mazandaran University of Medical Sciences under the code IR. MAZUMS. REC. 95. 1555. The research was started after registration in the Iranian registry of clinical trials under the code IRTC 2016112224606 N 2 and also written consent was obtained from all the patients.

2.2. Selection of the patients

All trauma patients who referred to the emergency department and needed PSA were included in the study. Patients under 18 and over 60 years old, patients with American Society of Anesthesiologists physical status classification of 3 or above, intoxicated trauma patients, patients with head trauma, patients with addiction history, pregnant women, patients with blood pressure lower than 90 mm Hg, pulse oximetry lower than 90%, pulse rate lower than 60 and patients with allergies or contraindications for fentanyl, propofol and ketamine were excluded from this study.

2.3. The study protocol

Patients were divided into two groups of propofol fentanyl (PF) and propofol ketamine (PK).

PF group was given 1 μg/kg fentanyl in 10 ml normal saline and the group PK was given 1 mg/kg ketamine in 10 ml normal saline. Both groups were given 0.5 mg/kg propofol. Randomization was performed using a computer assisted randomization table. Propofol was administered in both groups but ketamine and fentanyl were prepared in two separate syringes only labeled with a number, each patient was assigned a number by the emergency department pharmaceutic nurse based on randomization table and based on that number, a syringe was ordered by the resuscitation room nurse who was unaware of the type of the medication. The emergency medicine assistant who recorded their results, the physician who performed the procedure and all the patients were unaware of the medications. Only the study administrator had access to the unblended randomization codes, which were not used during the study.

2.4. Outcome assessment method

After administrating the medications, the depth of sedation was divided into four levels based on the criteria of the joint commission (TJC). Level 1: minimal sedation during which the patients obey the orders, but their cognitive functions and physical coordination may be impaired. Level 2: moderate sedation during which patients respond purposefully to verbal commands and show withdrawal reflection to pain. Level 3: deep sedation during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. They may need assistance in maintaining a patent airway. Level 4: general anesthesia during which patients are not arousable even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Cardiovascular function may be incurred, too. Pain severity is categorized from 0 to 10 based on visual analogue scale (VAS), blood pressure, heart rate, respiratory rate and O_2 saturation were measured before starting PSA and 15, 30 and 120 min after the initiation of PSA. The time interval between drug injection and the time when the patient leaves the recovery room and does not require accurate and close monitoring any more has been measured and

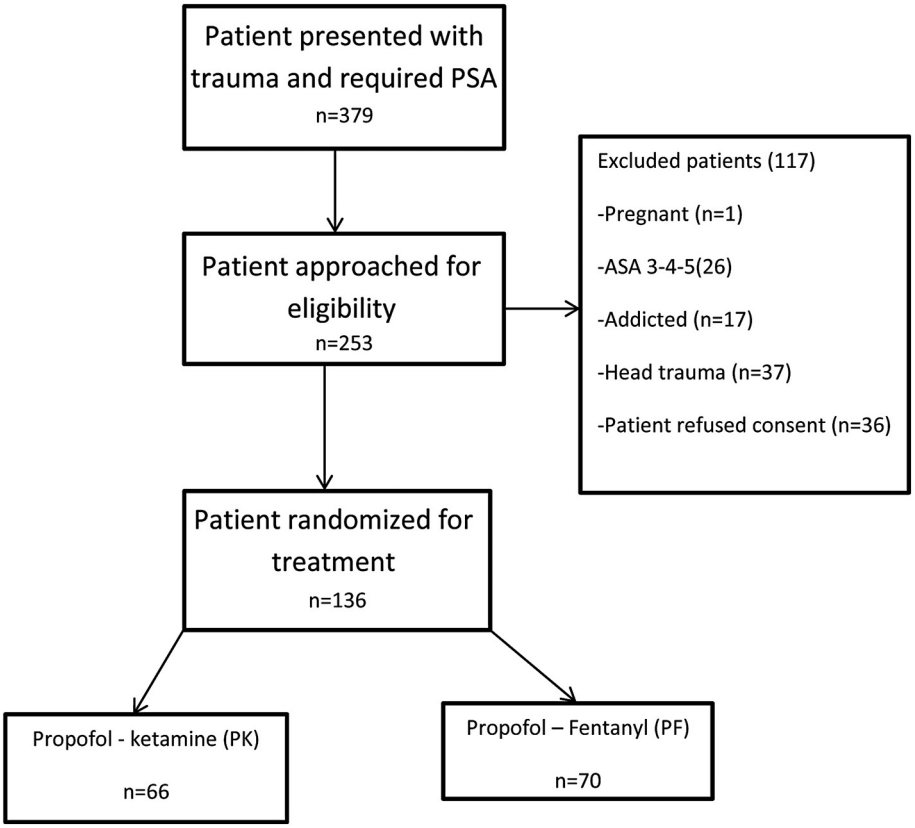

Fig. 1. Flow diagram of patients selection.

Please cite this article as: Aminiahidashti H, et al, Comparison of the combination of propofol–fentanyl with combination of propofol–ketamine for procedural sedation and analgesia..., American Journal of Emergency Medicine (2018), https://doi.org/10.1016/j.ajem.2018.01.080