The effect of two analgesia methods on the satisfaction level of trauma patients in the emergency ward.

Abstract

The nature of diseases that require interventional procedural and appropriate analgesia and sedation in emergency cases is an integral and important part of the field of emergency medicine. Using sedation and analgesia.
5.The study was a double-blinded randomized clinical trial (RCT)
6.The pain intensity mean and standard deviation before sedation in group A and group B were 8.9±1.0 and 8.9±1.3, respectively,
The results showed that both medicinal combinations (thiopental-fentanyl and midazolam-fentanyl) caused appropriate sedation. However, the midazolam-fentanyl combination resulted in less pain intensity for the patients after consciousness, but it did not make a difference in the patient's satisfaction with the conducted procedures.

Keywords: *Analgesia, Sedation, Thiopental, Fentanyl, Midazolam, Emergency ward.*

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Introduction

The emergency department as the frontline of providing services to patients, especially patients with the need for interventional procedures, is of great

they may discourage the person from continuing the treatment or can end with unpleasant memories.

The onset of its sedative effect is 1 to 2 minutes and the duration of the effect is between 30 and 60 minutes.

to assess their satisfaction with treatment in this department so that required changes can be made in the training method, if necessary.

Moreover, investigating the reasons to visit the emergency department in both groups showed no significant difference between the two groups (p>0.05).(table2)

Materials and methods

This study was a double-blinded RCT, and the study protocol was registered on the IRCT website. The population consisted of the patients who visited the emergency department of Imam Khomeini Hospital in Sari in 2018-2019. Considering the satisfaction level of 92% in the study of Zed et al., [8] in the emergency department of a general hospital, the sample size was obtained of 113 people. Finally, given the sample loss of 10%, the sample size was calculated to be 124 people. The patients aged between 16-60 years had dislocations or fractures in the upper limbs and needed painful treatment procedures. The patients with underlying heart and lung diseases, high blood pressure, substance abuse, taking painkillers and narcotics within a few hours before visiting the department, pregnant women, people with multiple traumas, and people under 16 and above 60 were excluded from the study. The patients were investigated in two random groups; the first group received fentanyl-thiopental and the second group received fentanyl-midazolam. Checklists were prepared, with the name of a group based on random numbers. The checklists were placed in the CPR room, and a checklist was filled out for any patient with the inclusion criteria, and the patients were homogenized based on age, sex, and pain intensity. The dose of medicines was determined as follows:

group 1: Fentanyl (1 to 3 mg/kg) and thiopental (2 mg/kg) (n=62)

group 2: fentanyl (1-3 mg/kg) and midazolam (0.05 mg/kg) (n=62) [17].

The numeric rating scale was used to measure pain intensity. It assesses pain intensity based on patients' experience and verbal description, ranging between 1 and 10 [18]. The IOWA scale was used to measure the patients' satisfaction level with the treatment procedures [19]. It should be noted that the patients were explained the purpose of the study and written informed consent forms were obtained. The study was approved by the Ethics Committee of Mazandaran University of Medical Sciences under code 1397.111, and the Declaration of Helsinki was fully observed. Finally, the obtained data were analyzed using analytical tests such as the chi-square test in SPSS 20. The significance level was determined to be $p<0.05$.

Results

This study investigated 124 patients with dislocations and fractures in the upper limbs, who needed painful treatment procedures, in two groups of 62 (the group fentanyl-thiopental and the group fentanyl-midazolam). The results showed that the age range of the patients was between 16-50 years with a mean and standard deviation of 34.6±12.8 (Table 1).

Table 1. The participants' age

Total number of participants			
Variable	Minimum	Maximum	Mean±SD
Age (years)	16	50	34.6±12.8

Moreover, investigating the reasons to visit the emergency department in both groups showed no significant difference between the two groups ($p>0.05$).(table .2)

Table 2. Distribution of the reasons to visit the emergency department in both groups

Variable				**p-value**
		Fentanyl – midazolam	Fentanyl-thiopental	
		Frequency (%)	Frequency (%)	
The reason for	Shoulder dislocation	35 (56.5)	42 (67.7)	0.294
	Humerus fracture	8 (12.9)	8 (12.9)	
	Elbow dislocation	0 (0.0)	1 (1.6)	
	Forearm fracture	15 (24.2)	8 (12.9)	

	Wrist dislocation	2 (3.2)	0 (0.0)	
	Dislocation of hand bones	1 (1.6)	1(1.6)	
	Hand bones fracture	1 (1.6)	2 (3.2)	

Investigation of pre-sedation and post-sedation symptoms and signs, according to Table 3, shows that there is no significant statistical difference between pre-sedation and post-sedation symptoms and signs ($p<0.05$). (table3)

Table 3. pre-sedation and post-sedation symptoms and signs in the two groups

Variable				p-value
		Fentanyl-midazolam	Fentanyl-thiopental	
		Frequency (%)	Frequency (%)	0.476
Nausea and vomiting before sedation	No	62 (100.0)	60 (96.8)	
	Yes	0 (0.0)	2 (3.2)	
Nausea and vomiting after full consciousness	No	57 (91.9)	56 (90.3)	0.752
	Yes	5 (8.1)	6 (9.7)	
Sialorrhea before sedation	No	62 (100.0)	61 (98.4)	0.315
	Yes	0 (0.0)	1 (1.6)	
Sialorrhea after full consciousness	No	59 (95.2)	55 (88.7)	0.187
	Yes	3 (4.8)	7 (11.3)	
Dizziness before sedation	No	57 (91.9)	58 (93.5)	0.742
	Yes	5 (8.1)	4 (6.5)	
Dizziness after sedation	No	36 (58.1)	45 (72.6)	0.089
	Yes	26 (41.9)	17 (27.4)	

The comparison of pain intensity and vital signs in patients of the two groups understudy showed that the pre-sedation pain intensity means and standard deviation in the fentanyl-midazolam group were 8.9±1.0 and in the fentanyl-thiopental group 8.9±1.3, indicating no significant statistical difference ($p=0.877$). But, the pain intensity after full consciousness in the fentanyl-thiopental group (3.8±1.2) was significantly higher than in the fentanyl-midazolam group (3.1±1.1) ($p=0.002$). Regarding the vital signs, except for the patient's heartbeat after full consciousness, which was significantly higher in the fentanyl-midazolam group (85.5±10.3 vs. 79.8±9.0) ($p=0.001$), no statistically significant difference was observed between the two groups in other variables before and after sedation ($p>0.05$) (table 4).

Table 4. Comparison of pain intensity and vital signs in the two groups

Variable	**Fentanyl-midazolam**	**Fentanyl-thiopental**	**p-value**
	mean±SD	mean±SD	
Pain intensity before sedation	8.9±1.0	8.9±1.3	0.877
Pain intensity after full consciousness	3.1±1.1	3.8±1.2	0.002
Hear rate before sedation	95.6±13.2	91.9±11.9	0.109
Heart rate after full consciousness	85.5±10.3	79.8±9.0	0.001
Systolic blood pressure before sedation	126.3±12.4	123.2±10.5	0.130
Systolic blood pressure after full consciousness	119.6±9.6	117.8±8.5	0.269

Diastolic blood pressure before sedation	76.7±9.9	77.1±9.00	0.813
Diastolic blood pressure after full consciousness	72.8±8.9	72.6±7.6	0.871
Respiratory rate before sedation	18.0±2.2	17.5±1.9	0.132
Respiratory rate after full consciousness	15.1±2.1	15.1±2.2	0.933
Oxygen saturation before sedation	98.7±1.3	98.7±1.3	0.893
Oxygen saturation after full consciousness	99.0±1.2	99.4±0.9	0.076

Finally, the patient's satisfaction with the procedures was assessed based on the IOWA scale. The results showed that the satisfaction means and standard deviation of patients in the fentanyl-midazolam group were 21.7±8.2 and in the fentanyl-thiopental 22.5±7.2, indicating no significant statistical difference (p=0.546) (table 5).

Table 5. Patients' satisfaction level with the procedures

Variable	**Fentanyl-midazolam**	**Fentanyl-thiopental**	**p-value**
	mean±SD	mean±SD	
Patient's satisfaction level	21.7±8.2	22.5±7.2	0.546

The most common reasons to visit the emergency department in this study were dislocation of the shoulder (77 patients (62.1%)), forearm fracture (23 patients (18.5%)), humerus fracture (16 patients (12.9%)), fracture of hand bones (3 patients (2.4%)), dislocation of wrist and dislocation of hand bones (2 patients for each (1.6%)) and dislocation of the elbow (1)patient .

In Arhami et. al.'s study, the mean age of patients was 27.3±8.9 years 93 patients (93%) were male and 7 patients (7%) were female. The difference can be caused by the fact that they only investigated dislocation of the shoulder, which occurs more in lower ages and among men [22].

1-In 2018 an article puplished by Abdolrazaghnejad.et,al.[24] That study was designed to investigate and identify the disadvantages and advantages of using each drug to be able to make the right choices in different clinical situations for patients while paying attention to the limitations of the use of these analgesic drugs.[24].

2 In a double-blind randomized placebo-controlled trial study conducted by Mohammadshahi et al.[23] in 2019, to investigate the effect of intranasal ketamine administration for narcotic dose decrement in patients suffering from acute limb trauma in emergency department. Ninety-one patients with mean age of 31.59 ± 11.33 years were enrolled (38.8% female). The number of requests for supplemental medication was significantly lower in patients who received ketamine (12)patients (30%) than those who received placebo (27 patients (67.5%)) (p = 0.001). It was likely that low-dose IN ketamine is effective in reducing the narcotic need of patients suffering from acute limb trauma.[23]

3-A systematic review entilted" effectiveness of pain management among trauma patients in the emergency department," was conducted by Hana M.Abu-Snieneh .et al published on 2022 [25] . A total of 777 articles were retrieved, and eighteen were selected according to the inclusion criteria in this systemic review. This systemic review provides an overview of the effectiveness of pharmacological and nonpharmacological pain management in trauma patients in the emergency department. Analgesic treatment is an effective and ancient management strategy with drawbacks of associated side effects and intravenous administration. New strategies reported and applied by oral or nasal route administration with similar and better efficacies.

Discussion

The present study aimed to investigate 124 patients with dislocations or fractures of the upper limbs, which required painful treatment procedures. The patients were divided into two groups of 62 (fentanyl-thiopental and fentanyl-midazolam). Sedation level performed for the patients was medium in 121 cases (97.6%) and mild in 2 cases (1.6%), indicating no difference between the two groups. Pain intensity mean and standard deviation before sedation in the fentanyl-midazolam group and the fentanyl-thiopental group was 8.9±1.0 and 8.9±1.3, showing no significant difference (p=0.877). However, pain intensity after full consciousness in the fentanyl-thiopental (3.8±1.2) was significantly higher than in the fentanyl-midazolam group (3.1±1.1) (p=0.002).

the patient's satisfaction with the procedures was assessed based on the IOWA scale. The results showed that the satisfaction means and standard deviation of patients in the fentanyl-midazolam group were 21.7±8.2 and in the fentanyl-thiopental 22.5±7.2, indicating no significant statistical difference (p=0.546). Johnson et al., [20] conducted a prospective observational study and examined adult patients who received sedation in the emergency department for 20 months. The patients' satisfaction was measured after full recovery using the IOWA satisfaction with anesthesia scale. In the study, 163 patients participated in the study (with a mean age of 50.7 years). The mean score of their satisfaction level was 2.7. The satisfaction level was significantly different in the 4 most common sedation diets (p<0.001). The patients who received propofol with or without fentanyl reported the highest satisfaction level, and the patients who received nitrous oxide with or without opioids had the lowest satisfaction level. The results of the present study were not in line with the results of this study in which the patients' satisfaction levels were different. This can be due to the use of different drug combinations, patients with different etiologies, and patients' different demographic characteristics.

Arhami et al., [20] investigated the combination of lidocaine-midazolam-fentanyl in the control of pain caused by the displacement of anterior shoulder dislocation in 100 patients in 2018. One group of patients received midazolam-fentanyl-placebo and the other group of patients received midazolam-fentanyl-lidocaine. The results showed that the combination of fentanyl-midazolam caused effective sedation and reduced pain intensity to 7.7, and adding lidocaine to this combination had no effect. This result is in line with the result of the present study in which the pain intensity mean in the fentanyl-midazolam was reduced to 5.8, indicating that this combination can be effective in PSA conditions.

Before sedation, 2 patients (1.6%) had nausea and vomiting, which increased to 11 patients (8.9%) after full consciousness. Also, one case of sialorrhea (0.8%) was reported before sedation, which increased to 10 (8.1%) after sedation. Before sedation, dizziness was reported in 4 patients (3.2%), which increased to 43 patients (34.7%), showing no significant difference between the two groups before and after sedation (p>0.05). In 2018, Miquez Navarro C. et al., [16] conducted a study entitled effectiveness, safety, and satisfaction of sedatives in Spanish emergency department. A total number of 658 procedures were recorded. The effectiveness of 483 procedures was evaluated as good (7.4-72.79%), 138 procedures as medium (5.9-18.24%), and 14 procedures as weak (2.2%). The effectiveness was better when the physician performed deep sedation. 52 patients reacted to the medications, which mostly included gastrointestinal, nervous, and respiratory reactions. One patient needed intubation. Older children and deeper levels of sedation have been identified as independent risk factors for adverse reactions. 13 patients (5%) had a late reaction to the medications, which mostly included nausea and dizziness. Midazolam-ketamine was used for these patients. In addition to nausea and dizziness, sialorrhea was also observed in some patients, which requires more attention and providing complete information to the patients and their companions regarding these side effects.

Regarding vital signs, except for heartbeat rate after full consciousness, which showed a significant difference between the fentanyl-midazolam (85.5±10.3) and fentanyl-thiopental (79.8±9.0) (p=0.001), there was no significant difference in other variables before and after sedation (p>0.05). There was no significant difference in the reduced blood oxygen saturation between the two groups, which is more caused by fentanyl and its effects on the central nervous system [27] (fentanyl was used for both groups). However, this complication was relieved as soon as oxygen was administered and all patients recovered [21]. In a prospective double-blinded clinical trial, Amini Ahi Dashti et al., [19] compared the two combinations of propofol-fentanyl and propofol-ketamine in making sedation and analgesia on 136 traumatic patients (70 patients in the propofol-fentanyl (PF) and 66 patients in the propofol-ketamine (PK)). The patients in the propofol-fentanyl had more respiratory depression and reduced blood oxygen saturation. This result is in line with the results of the present study.

The most common reasons to visit the emergency department in this study were dislocation of shoulder (77 patients (62.1%)), forearm fracture (23 patients (18.5%)), humerus fracture (16 patients (12.9%)), fracture of hand bones (3 patients (2.4%)), dislocation of wrist and dislocation of hand bones (2 patients for each (1.6%)) and dislocation of elbow (1 patient (0.8%)). There was no significant difference between the two groups (p>0.05). Peter Zed et al., [7] performed a prospective and observational study on 113 patients from 1st of December 2003 to 30 November 2005 for 2 years in the emergency department of Vancouver General Hospital. Propofol was administered to all patients who underwent PSA (procedural sedation and analgesia) for any reason. The patients' mean age was 50 years and 62% of them were male. The most common procedure was orthopedic fracture and dislocation reduction (44%).

The study showed that the age means and standard deviation of the patients aged between 16-50 years were 34.6 ±12.8 years. The age mean and standard deviation of patients in the fentanyl-midazolam was 34.1±13.2 and in the fentanyl-thiopental was 35.1±12.5, indicating no significant difference (p=0.640). It showed the homogeneity of the two groups in terms of age. Also, 98 patients (79.0%) were male and 26 patients (21%) were female. 50 patients (80.6%) in the

fentanyl-midazolam were male and 12 patients (19.4%) were female. In the fentanyl-thiopental, 48 patients (77.4%) were male and 14 patients (22.6%) were female, indicating no significant difference (p=0.659) and homogeneity of gender distribution between the two groups. In Arhami et al.'s study, the mean age of patients was 27.3±8.9 years and 93 patients (93%) were male and 7 patients (7%) were female. The difference can be caused by the fact that they only investigated dislocation of the shoulder, which occurs more in lower ages and among men [22].

Conclusion

The results obtained in this study showed that both fentanyl-thiopental and fentanyl-midazolam drug combinations used provided adequate sedation. Nevertheless, the combination of fentanyl-midazolam brought less pain intensity for the patients after consciousness, but did not make a difference in the patient's satisfaction with the performed procedures.

Limitations

One of the limitations of this study is the short follow-up period of the patients. Also, most cases of reductions performed after the passage of time and the disappearance of the effect of sedative drugs may be associated with the start of pain again, which requires a longer follow-up due to the different half-lives of the drugs used.

Offers

It is recommended to conduct a multicenter study with a longer follow-up period to investigate the reversibility of pain in different drug regimens

Acknowledgement

We would like to express my gratitude to the nurses of the emergency ward of Imam Khomenie hospital in Sari . Iran.

conflict of interest

We have no conflict of interest in this study .

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