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Comparison of fentanyl and dexmedetomidine versus fentanyl and midazolam in procedural sedation for tube thoracostomy in emergency department – A randomized control study

Sarat Chandra Uppaluri[1], Anne Kiran Kumar[2], G. Suneel Kumar[3], Mohammed Ismail Nizami[3]*, Ashima Sharma[3]

[1]Department of Emergency Medicine, AIG Hospitals, Departments of [2]Anaesthesiology and [3]Department of Emergency Medicine, Nizam's Institute of Medical Sciences, Hyderabad, Telangana, India

Abstract:

OBJECTIVES: Effective sedation and analgesia during procedures not only provide relief of suffering but also frequently facilitate the successful and timely completion of the procedure. The aim of the study was to evaluate the efficacy of fentanyl and dexmedetomidine compared to fentanyl and midazolam in procedural sedation for tube thoracostomy in the emergency department (ED) in terms of analgesia and patient satisfaction with sedation during the procedure using Pain Numerical Rating Scale and a 7-point Likert-like verbal rating scale for comfort rating of sedation.

METHODS: A randomized control study was conducted in 64 subjects admitted to the ED. Tube thoracostomy was performed in patients after the decision for Intercostal drain (ICD) placement taken on radiographic and clinical assessment depending on their condition warranting it and after optimally stabilizing the patient in the ED. Of the total study participants that met the inclusion criteria, 32 participants randomly received dexmedetomidine and the other 32 received midazolam.

RESULTS: Pain rating scale means were 2.3 ± 1.12 and 4.4 ± 1.72, respectively ($P < 0.001$), in dexmedetomidine and midazolam groups. With regard to adverse effects, a statistically significant difference was seen with dexmedetomidine causing hypotension ($P = 0.04$) and midazolam causing desaturation ($P = 0.008$). The results also suggested that midazolam achieved sedation levels quicker than dexmedetomidine and this finding was statistically significant ($P < 0.001$). A statistically significant difference was observed ($P < 0.001$) with regard to mean patient verbal ratings at recovery of sedation satisfaction between the two groups, 6 ± 0.77 (dexmedetomidine group) versus 4.7 ± 0.8 (midazolam group).

CONCLUSIONS: When observed in terms of analgesia, anxiolysis, and better sedation, dexmedetomidine proved to be superior. Our study shows that this drug could be a better alternative to traditional benzodiazepines for procedural sedation in ED.

Keywords:

Dexmedetomidine, midazolam, pain rating scale, tube thoracostomy

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ORCID:
SCU: 0000-0002-6245-0387
AKK: 0000-0003-0075-4059
GSK: 0009-0002-0034-1422
MIN: 0000-0002-0377-5456
AS: 0000-0001-9646-9695

Address for correspondence:
Dr. Mohammed Ismail Nizami, Department of Emergency Medicine, Nizam's Institute of Medical Sciences, Panjagutta, Hyderabad, Telangana, India.
E-mail: ismail_nizami@rediffmail.com

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Box-ED section

What is already known about the study topic?

- Procedural sedation plays an important role in facilitating emergency procedures
- Choice of drugs depends on the goal to achieve anxiolysis, analgesia, or sedation with minimal adverse effects.

What is the conflict on the issue? Is it important for readers?

- Dexmedetomidine has not been much studied in the emergency settings for procedural sedation
- Although the existing few studies reported dexmedetomidine as a safe and effective agent, there is no sufficient data on its use in the emergency department.

How is this study structured?

- This was a single-center randomized prospective study with 64 patients, comparing combination of fentanyl and dexmedetomidine with that of fentanyl and midazolam for tube thoracostomy in the ED.

What does the study tell us?

- Dexmedetomidine proved to be superior in terms of analgesia, anxiolysis, and better sedation compared to midazolam
- It could be a better alternative to traditional benzodiazepines for procedural sedation in ED.

Introduction

Procedural sedation is a standard practice in the emergency department (ED).[1] The accepted definition of procedural sedation is the use of anxiolytic, hypnotic, analgesic, or dissociative medications to attenuate anxiety, pain, and motion. Chest traumas are a cause of significant mortality and morbidity. Ten percent of trauma-related deaths can be attributed to chest trauma.[2] Tube thoracostomy is the mainstay and sometimes a pertinent emergency procedure for patients with chest injuries. Tube thoracostomy is a painful procedure and adequate patient comfort is essential for cooperation and to increase the ease of the procedure.

The commonly used drug for sedation in tube thoracostomy is midazolam. It belongs to the benzodiazepines class of drugs and has amnestic, anxiolytic, sedative, and anti-convulsant properties by enhancing the inhibitory neurotransmitter, gamma-amino butyric acid.[3]

Dexmedetomidine is a drug not routinely used but it has achieved US Food and Drug Administration approval in 2003 for procedural sedation. It acts as an agonist at alpha 2 receptors in the brain leading to inhibition of the release of norepinephrine from synaptic vesicles. This causes postsynaptic inhibition of adrenoceptors causing sympatholysis and thereby bringing about anxiolysis, sedation, and analgesia.[4]

Our literature review found very few studies utilizing dexmedetomidine in ED.[5] It has been majorly confined to anesthesia faculties and intensive care unit (ICU) sedation. Hence, it was thought to explore this drug and compare it with its traditional counterpart, i.e. midazolam for procedural sedation in ED.

Methods

This double-blinded randomized control study was conducted in a tertiary care teaching medical institute in India. Approval from the institute ethics committee was obtained wide letter number EC/NIMS/2702/2021 dated June 17, 2021. Patients fulfilling the inclusion criteria were explained about the study and written informed consent was obtained. The sample size was calculated based on a difference of 2 in patients' satisfaction scores between groups (which would be the smallest clinically relevant difference) and the assumption of a population variance of $(2)^2$ as were considered in other similar studies,[6] a two-sided α of 0.05, and a power of 80%.

Sample size, $n = z^2 \sigma^2/\text{Power}^2$

The sample size thus calculated was 24 for each arm of the study. (z taken to be 1.96). A sample size of 64 (32 in each group) was contemplated to cover for any exclusions later due to patient noncooperation during the study or where anticipated adverse events would not respond to the protocolized remedial measures.

Inclusion criteria

Age above 18 years and <70 years of age, ASA grade I and II, and patients with chest trauma requiring ICD, including those with mild traumatic brain injury (Glasgow Coma Scale [GCS] score: 14–15).

As it is a bit rare to have an isolated chest injury in patients with trauma and also as our study was conducted during the pandemic, we thought to include only those patients with exclusive chest trauma, the numbers would not be sufficient to complete the study. Hence, we included those with mild traumatic brain injuries and bone fractures with relatively stable hemodynamics who could be optimized before the study.

Exclusion criteria

Pregnancy, hypotension – systolic blood pressure (SBP) <90 mmHg, known allergies to dexmedetomidine, midazolam, or fentanyl, patients with decompensated liver disease or renal impairment, patients with

moderate-to-severe traumatic brain injury (GCS score 13 or less), and history of alcohol or drug abuse were excluded from the study.

Tube thoracostomy was performed in patients depending on their clinical condition warranting it after optimally stabilizing the patient in the ED. Patients were shifted to the procedure room for thoracostomy and monitored throughout the procedure with Electrocardiogram (ECG), noninvasive blood pressure (NIBP), and SpO2. Patients were provided with supplemental oxygen and IV fluids based on the underlying condition. All the necessary emergency airway and resuscitation equipment and drugs were kept ready in the procedure room as usual.

The participant flow chart is shown in Figure 1. All 64 study participants who met the inclusion criteria received baseline analgesia with fentanyl 1 µg/kg upon arrival to the procedure room. Five min after receiving fentanyl, half of the patients randomly received dexmedetomidine and the other half received midazolam (after computer randomization). Study participants were blinded to the drug they received. All the drugs were prepared and instituted by the procedure room nurse who was not blinded to the study.

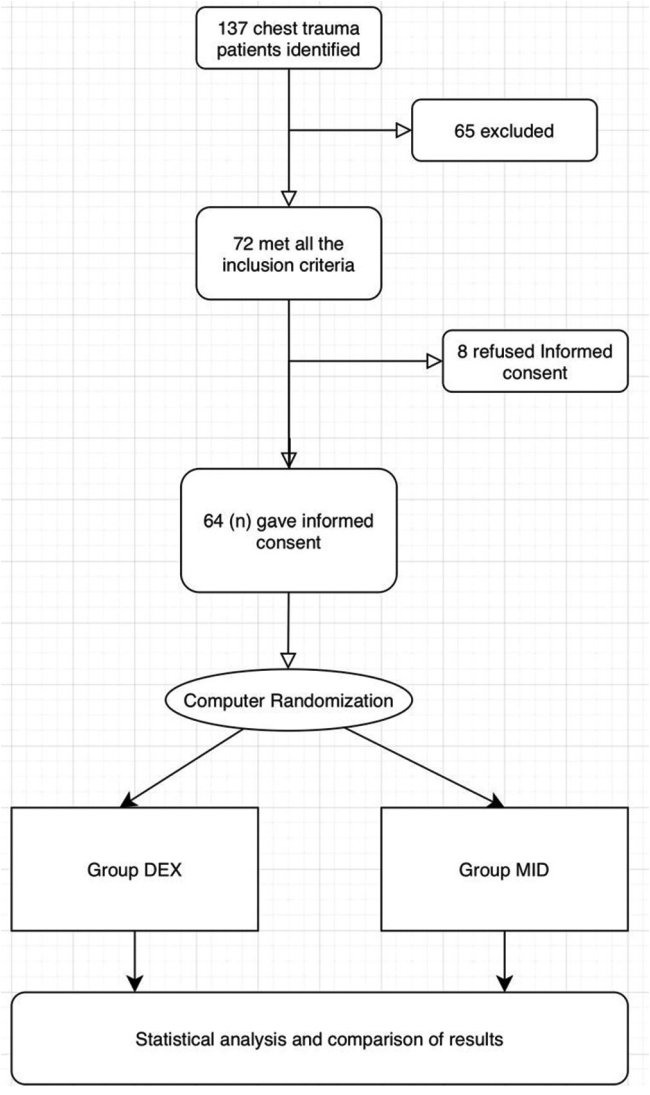

Figure 1: Patient flow diagram

In the dexmedetomidine group, the drug was given as an intravenous bolus dose of 1 µg/kg over 10 min and an infusion of 0.2 µg/kg/h and increased up to 0.7 µg/kg/h until the target sedation score was achieved. In the other group, midazolam was given as a 20 µg/kg intravenous bolus with repeated boluses of 0.5 mg IV as required [Figure 2], titrated to the sedation scale. Ramsay Sedation Scale (RSS) was used to assess the degree of sedation and a score of 3–4 was the target sedation level.

Local anesthetic infiltration was given with 2–3 ml of 2% lignocaine solution for the tube thoracostomy procedure after attainment of the target sedation level. The procedure was started 3–5 min after the infiltration and was done by a trained resident doctor with sufficient expertise and was not blinded to the study. A sedation level of 3–4 was maintained throughout the procedure. Time to achieve the target sedation level, total dose of the drug used, and total duration of the procedure were noted. Patient's hemodynamics was monitored throughout the procedure and during the postprocedural stay in the procedure room. A paramedic who was blinded to the drug administered, monitored the vitals as mentioned above, and reported and treated (under guidance) any adverse event.

Hypotension was defined in absolute terms as SBP of <80 mmHg or diastolic blood pressure of <50 mmHg or in relative terms as ≥30% decrease from prestudy drug infusion value. It was contemplated to be treated with mephentermine 3 mg boluses and 100 ml IV fluid boluses as needed.

Bradycardia was defined in absolute terms as <40 bpm or in relative terms as ≥30% decrease from the prestudy drug infusion value. It was contemplated to be treated with atropine 0.3 mg boluses as needed.

Respiratory depression was defined in absolute and relative terms as respiratory rate (RR) <8 per min or >25% decrease from baseline, respectively.

Desaturation was defined in absolute and relative terms as SpO2 <90% or 10% decrease from baseline for ≥30 s in spite of oxygen supplementation with face mask (as was required at the level from preprocedural period if any).

Airway support with bag mask and proper/further oxygen supplementation was contemplated to be

instituted if any of the above 2 complications were encountered.

Patients were monitored for 30 min postprocedure and assessed for consciousness, respiratory pattern, and hemodynamic stability by the paramedic. Time to this appropriate recovery, postprocedure was noted [Figure 3]. Patient analgesia [Figure 4] and satisfaction scores were documented using the Pain Numerical Rating Scale (PNRS) and a verbal rating scale for comfort rating of sedation by the paramedic just before shifting the patient to observation when their RSS score was 1. An 11-point scale from 0 to 10 was used to assess the quality of analgesia and a 7-point Likert-like verbal rating scale for comfort rating of sedation during the procedure.

The data drawn was expressed as mean ± standard deviation, median and interquartile ranges, or numbers and percentages. Normal distribution of data was assessed using Shapiro–Wilk and Kolmogorov–Smirnov tests. The means were compared and analyzed with independent samples *t*-test or one-way ANOVA test wherever required. Nonparametric test such as Chi-square test was performed for gender distribution and ASA grades. Medians and interquartile ranges also were analyzed and compared between both drug groups for PNRSs and verbal rating scales using Mann–Whitney test. For statistical analysis, IBM SPSS statistics software, version 27 (International business machines, New York, USA) for Windows was used. $P < 0.05$ was considered statistically significant.

Results

Score	Level of Sedation
1	Patient is anxious and agitated or restless, or both
2	Patient is co-operative, oriented, and tranquil
3	Patient responds to commands only
4	Patient exhibits brisk response to light tactile stimuli or loud auditory stimulus
5	Patient exhibits sluggish response to light tactile stimuli or loud auditory stimulus
6	Patient exhibits no response

Figure 2: Ramsay sedation scale

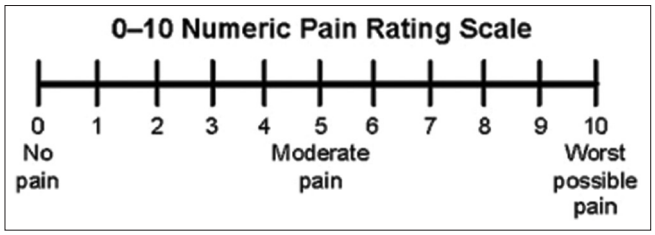

Figure 3: Pain numerical rating scale

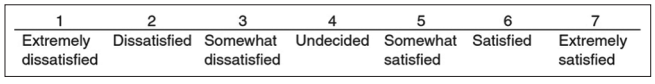

Figure 4: Likert like verbal rating scale

Both groups were comparable with regard to patient demographics and baseline vitals before administering study drugs. The mean doses of dexmedetomidine and midazolam used in the study were 68.5 ± 25.6 μg and 2.06 ± 1.11 mg, respectively [Table 1]. There was no statistically significant difference between the duration of the procedure and mean time to adequate recovery postprocedure between the two groups and both groups were comparable in terms of duration of tube thoracostomy procedure. The results suggested that midazolam achieved sedation levels quicker than dexmedetomidine and this finding was statistically significant ($P < 0.001$). In the dexmedetomidine group, 17 patients achieved an initial target RSS level of 3 while 15 achieved a level of 4. In the midazolam group, 8 patients achieved an initial target RSS level of 3 while 24 achieved a level of 4 [Table 2].

Table 1: Demographic characteristics and mean doses of study drugs

Baseline characteristics	Dexmedetomidine (*n*=32)	Midazolam (*n*=32)	*P*
Mean age (years)	39.38	35.42	0.31
Gender			
Male	27	28	0.75
Female	5	4	
Mean weight (kg)	61.37±9.17	62.96±11.9	0.5
ASA grade			
Grade I	21	22	0.64
Grade II	11	10	
Mean doses	68.5±25.6 μg	2.06±1.11 mg	

ASA: American Society of Anesthesiologists

Table 2: Times for sedation onset and recovery, duration of procedure, and initial target Ramsay Sedation Scale in both groups

	Dexmedetomidine	Midazolam	*P*
Mean time to achieve sedation (min) (RSS 3–4)	14.8±3.95	10±4.20	<0.001
RSS achieved			
3	17	8	
4	15	24	
Mean duration of the procedure (min)	18.1±5.99	18±4.13	0.91
Mean time to recovery (min)	16.1±21.33	16.1±6.46	0.98

RSS: Ramsay Sedation Scale

Table 3: Patient's pain and satisfaction scores

Pain on numerical rating scale (PNRS)			
Numerical Rating Scale	Dexmedetomidine	Midazolam	*P*
Mean	2.34±1.12	4.43±1.72	<0.001
Median	2	5	<0.001
IQR	2	3	
Satisfaction on Verbal Rating Scale			
Verbal Rating Scale	Dexmedetomidine	Midazolam	*P*
Mean	6.09±0.77	4.78±0.8	<0.001
Median	6	5	<0.001
IQR	1	1	

The patients' pain score is shown in Table 3. The means were 2.3 ± 1.12 and 4.4 ± 1.72, respectively ($P < 0.001$), in both the groups. Comparing the medians between the two groups also revealed a statistically significant difference between the two groups ($P < 0.001$). On a verbal patient satisfaction rating scale, in the dexmedetomidine group, the mean was 6 ± 0.77 and in the midazolam group, the mean was 4.7 ± 0.8 ($P < 0.001$). Median values were 6 and 5, respectively, in each of the groups ($P < 0.001$). Both yielded statistical significance.

In the dexmedetomidine group, 4 patients had hypotension, 1 had hypertension, 3 had bradycardia, and 1 had tachycardia. In the midazolam group, 6 had desaturation. A statistically significant difference was seen with dexmedetomidine causing hypotension ($P = 0.04$) and midazolam causing desaturation ($P = 0.008$).

Discussion

Procedural sedation and analgesia help us to alleviate pain and anxiety during a procedure and also aid in the smooth execution of the procedure as it ensures patient cooperation which is vital in performing such procedures.

The dose regimen of both dexmedetomidine and midazolam used in our study was similar to that used by Alhashemi *et al*.,[6] Sethi *et al*.,[7] and Karaaslan *et al*.[8] in their studies.

In our study, the mean doses of dexmedetomidine and midazolam used were 68.5 ± 25.6 μg and 2.06 ± 1.11 mg, respectively, with a relative sedation ratio of about 30:1 for dexmedetomidine to midazolam. Most of the patients in both groups required more than the initial loading doses of these drugs for appropriate clinical effect. Similar mean doses of dexmedetomidine and midazolam for a titrated RSS level of 3–4 as in our study were observed in the studies by Alhashemi *et al*.[6] (79.5 μg and 1.5 mg) and Sethi *et al*.[7] (62.36 μg and 3.49 mg) while higher mean doses of midazolam were observed in the study by Liao *et al*.[9] (66.2 μg and 5.8 mg). The subjects in this study were not pretreated with opioids such as fentanyl. This discrepancy in mean doses to achieve sedation could probably be partly attributed to the synergistic depressive effect of midazolam on consciousness when used in conjunction with opioids.

In the context of targeted sedation levels intended before starting the procedure, the patients in the midazolam group had relatively higher targeted sedation levels. This could probably be attributed to the nature of drug delivery. The patients in the dexmedetomidine group received the drug as an infusion whereas the patients in the midazolam group received the drug in the form of repeated boluses. We can also infer that due to the better titrability of dexmedetomidine with an infusion regimen, attainment to a specific target sedation level was easy and served without risk of over sedation. This titrability to achieve targeted sedation levels with dexmedetomidine would be beneficial for performing different procedures in ED without the risk of overt excessive sedation and antecedent complications. Our study findings, in contrast, differed with a study by Yu *et al*.,[10] in which the Observer's Assessment of Alertness/Sedation Scale score was significantly lower for patients administered dexmedetomidine compared to those who received midazolam.

The mean times to achieve the target sedation level were 14.8 ± 3.95 min and 10 ± 4.20 min in the dexmedetomidine and midazolam groups, respectively. Even in the study by Sethi *et al*.,[7] the time to achieve sedation was significantly lower in the midazolam group where similar dosage regimens were followed. This finding could be attributed to the longer duration of administration of bolus dose of dexmedetomidine over 10 min as compared to midazolam. The repeat boluses of midazolam were administered in shorter intervals which was lesser than the time for bolus of dexmedetomidine. This could be the reason for the shorter duration for achieving sedation seen in the midazolam group.

In the study by Masoumi *et al*.,[11] where infusion regimen over a period of time was followed for administration of midazolam and fentanyl (0.05 mg/kg midazolam and 1 μg/kg fentanyl over 10 min) similar to dexmedetomidine (1 μg/kg followed by 0.2 μg/kg/h for 10 min) faster procedural sedation occurred in the dexmedetomidine group (8.60 ± 2.3 min vs. 11.27 ± 3.57 min, $P = 0.001$) substantiating that nature/type of drug dose delivery regimen has a bearing on onset time for achieving sedation. The titrated infusion of bolus dose of dexmedetomidine over a period of time is usually done to avoid the documented side effects such as bradycardia and hypotension and is often followed by a maintenance infusion regimen as needed as opposed to bolus doses of midazolam.

Both the study groups were comparable in terms of time to adequate recovery post sedation in spite of the infusion regimen for dexmedetomidine versus bolus doses for midazolam. This might be attributable to the better pharmacokinetic profile of dexmedetomidine for short-duration infusions and its context-sensitive half-life, which ranges from 4 min after a 10 min infusion to 250 min after an 8 h infusion.[12] As opposed to our study findings where the recovery periods were similar in both groups, a study by Alhashemi *et al*.[6] showed earlier recovery with midazolam than dexmedetomidine whereas the study by Sethi *et al*.[7] demonstrated earlier recovery with dexmedetomidine.

In our study, the mean numerical rating scales for pain at recovery were 2.3 ± 1.12 and 4.4 ± 1.72 in the dexmedetomidine and midazolam groups, respectively. More than 60% of the patients in the dexmedetomidine group reported pain levels of 1 or 2. Dexmedetomidine when used with opioids exhibits synergy in antinociceptive (analgesic) effect due to its alpha-2 receptor agonistic activity. Similar findings are observed in the studies by Sethi *et al*.,[7] Masoumi *et al*.,[11] and Parikh *et al*.[13] which demonstrated dexmedetomidine to have better analgesic effect over midazolam. In the systematic review done by Barends *et al*.,[14] 2 out of the 8 studies demonstrated better analgesia with dexmedetomidine compared to midazolam and the other 6 studies did not show a significant difference between the two groups.

In our study, the mean verbal satisfaction ratings of quality of sedation after recovery from sedation were 6 ± 0.77 and 4.7 ± 0.8 in the dexmedetomidine and midazolam groups, respectively. Similar findings of better patient satisfaction with dexmedetomidine were demonstrated in other similar studies by Alhashemi *et al*.,[6] Sethi *et al*.,[7] and Parikh *et al*.[13] In the systematic review by Barends *et al*.,[14] 4 out of 8 studies showed better patient satisfaction in the dexmedetomidine group as compared to the midazolam group and the other 4 studies did not show a significant difference in patient satisfaction among both the groups.

Even in ICUs, dexmedetomidine infusion is said to cause cooperative sedation akin to the natural state of sleep with easy rousability. The better patient satisfaction in the dexmedetomidine group could also be partly attributed to the additional analgesic property of dexmedetomidine. Satisfaction with a particular sedation procedure would be in terms of anxiolysis, amnesia, analgesia, and a better quality of sedation which seems to be better with dexmedetomidine and so can be used as the preferred drug for procedural sedation and analgesia in ED. An interesting finding was that the majority of the patients in the midazolam group had no recall of the procedure when asked again after 24 h. This property of anterograde amnesia of midazolam helped the patients to forget the traumatic episode. This was not observed in the dexmedetomidine group.

With regard to adverse events, hypotension was reported in four patients in the dexmedetomidine group (responded quickly to fluid bolus) which was statistically significant (P = 0.04). Other adverse events such as hypertension, bradycardia, and tachycardia were not statistically significant and did not require any intervention and were short-lived. Hypotension and bradycardia are usually associated with higher bolus doses of dexmedetomidine and rapidity of infusion. Our present study findings were similar to a study by Sinnott *et al*.,[15] in which dexmedetomidine was used in 103 patients for various indications. About 52.4% of patients experienced a composite adverse event with hypotension occurring in 39.8% and bradycardia occurring in 17.5% of patients. In spite of the high incidence of these adverse events, only 8 of them required termination of the drug infusion.

In the midazolam group, 6 had desaturation which was statistically significant (P = 0.008). Desaturation might be due to subclinical respiratory depression, i.e. a decrease in tidal volume rather than an overt decrease in RR which would not have been appreciated. This is a known complication of benzodiazepines (midazolam) all the more when given in conjunction with opioids (fentanyl). The incidence of this event is seen lesser in the dexmedetomidine group because it does not significantly affect the respiratory drive and it is probably the only sedative approved for administration in nonintubated ICU patients and the infusions can be continued following extubation as well.

Lower SpO2 levels without desaturation were seen in the midazolam group in similar studies comparing dexmedetomidine and midazolam by Alhashemi *et al*.[6] and W Liao *et al*.[9] However, a considerable number of patients are at risk of hypoxemia with procedural sedation in ED.[16] Patients in midazolam had lesser number of other adverse events as compared to dexmedetomidine apart from the desaturation episodes in 6 patients. Patients were adequately/additionally supplemented with oxygen through a simple face mask upon desaturation. None of the patients had serious adverse events such as respiratory depression or cardiac arrest and none required mechanical ventilation.

Similar to the findings in our study, recent studies using dexmedetomidine for procedural sedation in ED found it to be advantageous in terms of better parental satisfaction, analgesia, sedation depth (intranasal dexmedetomidine vs. intranasal esketamine in children),[17] and oxygen saturation (ketodex vs. ketofol vs. ketamine)[18] without any major adverse events.

A systematic review of dexmedetomidine usage in the ED concluded that although some studies reported it as a safe and effective drug in procedural sedation, sufficient data is still required to assert its role in this regard. Our current study partially addresses this issue with regard to its use for procedural sedation, i.e. tube thoracostomy in ED.[19]

Limitations

Our study included a small number of participants and the drugs were used only for procedural sedation in tube thoracostomies.

Conclusion

Our study showed that dexmedetomidine was superior

to midazolam in providing better analgesia and patient satisfaction for procedural sedation in ED. Although there were adverse events such as hypotension occurring more frequently with dexmedetomidine, they were not serious enough to terminate infusion and were transient. Midazolam showed respiratory side effects although easily manageable. When observed in terms of analgesia, anxiolysis, and better sedation, dexmedetomidine proved to be superior.

Not many studies have utilized dexmedetomidine in emergency rooms and our study shows that this drug could be a better alternative to traditional benzodiazepines for procedural sedation in ED. As our study limited the usage of the drug to tube thoracostomy, we opine that many such studies might be required to assess the efficacy and safety of dexmedetomidine when expanded to various other emergency procedures.

Author contributions statement

1. Dr Sarat Chandra Uppaluri-Conceptualisation and data collection
2. Dr Anne Kiran Kumar-Design and data analysis
3. Dr G Suneel Kumar-Data interpretation and writing original draft
4. Dr Mohammed Ismail Nizami-Review and editing
5. Dr. Ashima Sharma-Language and review.

Conflicts of interest

None Declared.

Ethical approval

Written prior approval obtained from the Institutional Ethics Committee of Nizam's Institute of Medical Sciences (Review letter number EC/NIMS/2702/2021) dated June 17th, 2021.

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