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Propofol versus midazolam for procedural sedation in the emergency department: A study on efficacy and safety

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ABSTRACT

Background: Procedural sedation for painful procedures in the emergency department (ED) can be accomplished with various pharmacological agents. The choice of the sedative used is highly dependent on procedure- and patient characteristics and on personal- or local preferences.

Methods: We conducted a multicenter retrospective cohort study of procedural sedations performed in the EDs of 5 hospitals in the Netherlands over a 4 year period to evaluate the efficacy- (success rate of the intended procedure) and safety (incidence of sedation (adverse) events) of propofol sedations compared to midazolam sedations.

Results: A total of 592 ED sedations were included in our study. Patients sedated with propofol (n = 284, median dose 75 mg) achieved a deeper level of sedation (45% vs. 25% deep sedation, $p < 0.001$), had a higher procedure success rate (92% vs. 81%, $p < 0.001$) and shorter median sedation duration (10 vs. 17 min, $p < 0.001$) compared to patients receiving midazolam (n = 308, median dose 4 mg). A total of 112 sedation events were registered for 99 patients. Transient apnea was the most prevalent event (n = 73), followed by oxygen desaturation (n = 18) airway obstruction responsive to simple maneuvers (n = 13) and hypotension (n = 6). Propofol sedations were more often associated with the occurrence of apnea's (20% vs. 10%, p = 0.004), whereas clinically relevant oxygen desaturations (<90%) were found more often in patients sedated with midazolam (8% vs. 1%, p = 0.001). No sedation adverse events were registered

Conclusion: Propofol is more effective and at least as safe as midazolam for procedural sedation in the ED.

1. Introduction

Procedural sedation and analgesia (PSA) is defined as a technique of administering sedatives or dissociative agents with or without analgesics in order to induce a state that allows the patient to tolerate unpleasant procedures while maintaining cardiorespiratory function [1]. This allows many procedures to be performed in the emergency department instead of the operating theatre. However, PSA imposes an independent risk factor for morbidity and mortality in addition to the procedure itself [2]. Practice guidelines have therefore been developed by interdisciplinary professional organizations in most countries to ensure safe sedation outside the operating theatre [1,3-5]. Although these guidelines provide clear recommendations about pre-procedural screening, monitoring during sedation and about discharge criteria, recommendations about the pharmacological agents that should be used are less unequivocal. Various agents are available (e.g. propofol, benzodiazepines, ketamine), and the ultimate choice of the sedative agent is highly dependent on procedure characteristics (e.g. estimated duration of procedure, required sedation depth), patient characteristics (e.g. co-morbidities, allergies, fasting state) and on personal- or local preferences.

Since most procedures in the ED for which PSA is indicated (e.g. fracture reposition, joint relocation, electro cardioversion or abscess drainage) are short in duration, a pharmacological agent with a rapid onset and short recovery time (such as propofol) may often be preferable above longer acting agents (such as benzodiazepines) [6-10]. Although both benzodiazepines and propofol have their potential advantages and disadvantages for procedural sedation in the ED, literature directly comparing the success rate and complications of both sedatives in one population is scarce, and the conclusions drawn are limited by small study populations [7-12]. Consequently, it is largely unknown how the

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efficacy and safety profile of propofol stands out to benzodiazepines for procedural sedation in the ED. Therefore, the objective of our present study is to compare and evaluate the safety and effectiveness of propofol and midazolam for procedural sedation in the ED.

2. Methods

2.1. Study design and subjects

We performed a multicenter retrospective cohort study using the procedural sedation registries of the EDs of 1 university hospital, 2 teaching hospitals and 2 community hospitals in the northern region of the Netherlands. Participating hospitals are listed in Table 1. All hospitals register ED procedural sedations using the registration template provided by the Netherlands Society of Emergency Medicine (NSEP, Nederlandse Vereniging voor Spoedeisende Hulp Artsen), see Supplementary Table 1.

2.2. Procedural sedation practice

In all participating hospitals, sedations were carried out by Emergency Physicians trained in the conduct of procedural sedation according to the Dutch national guideline for sedation outside the operating theatre [5]. This guideline describes the procedure of pre-procedural screening, monitoring, sedation, and discharge: For each patient, age, gender, body weight, body mass index (BMI), medical history, medication use, allergies, fasting state, American society of Anaesthesiologists (ASA) score and difficult mask ventilation (DMV) score are recorded prior to sedation. It prescribes that all patients are monitored using pulse oximetry, 3-lead electrocardiogram (EKG) and non-invasive blood pressure measurements. End tidal CO_2 monitoring ($etCO_2$) is optional. Pre-oxygenation is a standard procedure for all ED sedations. (The amount of) oxygen suppletion during the procedure, as well as the choice of sedation medication and the applied dosages are left at the discretion of the treating physician. Medication (dosage) applied, vital signs during- and after sedation, sedation depth, success- and recall of the procedure as well as any sedation (adverse) events and subsequent treatments are registered after the procedure on the previously mentioned registration template.

2.3. Subjects

For our present study we analyzed the sedation registration data of all adult patients (≥18 years) who underwent ED procedural sedation with either midazolam or propofol in the period between 17 and 02-2011 (first entry in sedation register) and 31-6-2015. Excluded were patients < 18 years, patients who received muscle relaxants additional to their sedative, patients who were sedated with nitrous oxide, etomidate, or ketamine and patients who received more than one sedative or hypnotic (e.g. combination of propofol and ketamine).

2.4. Data acquisition

Data were collected from the original sedation registration forms in each of the participating hospitals by the investigators (YS, HL, FB, MB and AP). Crosschecking of correct data entry was performed by two investigators (YS and HL). Based on previous studies we chose to subtract the following patient- and sedation-characteristics from the registration forms: Age, gender, bodyweight (kg), body length (cm), BMI, medical history, allergies, current use of medication, ASA classification, difficult mask ventilation score (DMV score), time passed since last meal, sedative used (including dose), analgesics used (including dosages), sedation depth during the procedure according to the physician delivering the sedation ("not sedated", "light sedation", "moderate sedation", "deep sedation" or "total sedation"), total duration of the sedation, vital parameters (including respiratory rate, systolic blood pressure (SBP), heart rate and (when available) $etCO_2$) prior to, during and after the sedation, any sedation (adverse) events and any performed interventions in response to sedation (adverse) events.

Definitions used to score sedation depth came from the national guideline [5]: Light sedation is defined as anxiolysis with lightly diminished consciousness levels wherein the patient still reacts to verbal stimuli and cardiopulmonary functions are unaffected. Moderate sedation is defined as a decrease in consciousness wherein the patient is still reactive to directed vocal or tactile stimuli and airway reflexes are unaffected. Deep sedation is defined as decrease in consciousness with no reaction to verbal stimuli but wherein the patient is reactive to repeated or painful tactile stimuli. Airway reflexes and ventilation can be affected. A patient with total sedation is not reactive to painful stimuli. Airway reflexes are diminished to non-existent, pulmonary and cardiovascular depression may occur.

2.5. Outcome measures

Primary outcome was defined as both efficacy- (measured by the success rate of the intended procedure) and safety (measured by the incidence of sedation (adverse) events) of sedation. Sedation events were defined as: agitation, vomiting, airway obstruction alleviated by simple maneuvers, apnea > 20 s responding to verbal or tactile stimulus, hypotension (defined as an SBP < 90 mm Hg), and oxygen desaturation (defined as oxygen saturation measured with pulse oximetry < 90% for >60 s). Sedation adverse events were defined as: Aspiration, laryngospasm or other airway obstruction not alleviated by simple airway maneuvers, need for intubation, hospitalization and mortality.

3. Ethics

As our study only involved retrospective evaluation of routinely recorded patient data, this type of study was determined to be exempt research by the ethical review board of the Medical Centre Leeuwarden (protocol number WMO2015/121).

3.1. Statistical analysis

Continuous data are presented as median with interquartile range (IQR) whereas nominal data are presented as absolute numbers and percentages. Missing data are reported in the results section according to the STROBE guideline [13]. Normality of data was tested with the Kolmogorov-Smirnov test with Lilliefors' correction. The Chi-square test was used for comparison of nominal variables and the independent *t*-

Table 1
Characteristics of participating hospitals.

Name hospital	Number of ED visits	Type hospital	Start date sedation registry	Total inclusions	Propofol sedations	Midazolam sedation
UMCG	32.000	University	17-02-2011	145	20	125
MCL	26.000	Teaching	17-09-2012	195	185	10
Isala	35.000	Teaching	07-01-2012	169	20	149
WZA	14.000	Community	09-01-2012	62	38	24
NS	13.000	Community	14-12-2014	21	21	–

UMCG, University Medical Centre Groningen, Groningen, the Netherlands; MCL Medical Centre Leeuwarden, Leeuwarden, the Netherlands; Isala, Isala hospital, Zwolle, the Netherlands, WZA; Wilhelmina Hospital, Assen, the Netherlands; NS; Hospital Nij Smellinghe, Drachten, the Netherlands.

test and Mann Whitney test were used when appropriate for comparison of continuous variables across treatment groups. Loglinear analysis was performed to investigate possible interactions of nominal variables (sedation depth, oxygen supplementation, opioid co-medication) on the association of the type of sedative (propofol or midazolam) on predefined endpoints. For all tests a $p \leq 0.05$ was considered statistically significant. All tests are two-tailed. Statistical analysis was performed using IBM SPSS Statistics Premium' V 22 for Windows (IBM Corp. released 2011. IBM SPSS Statistics for Windows, version 22.0. Armonk, NY: IBM Corp.)

4. Results

4.1. Study population

A total of 814 sedations were registered in the PSA registries of the 5 participating hospitals during the study period. Two hundred and four sedations did not fulfil the inclusion criteria (Fig. 1). Further results refer to the remaining 592 patients. See Tables 1 and 2 for participating hospital- and patient characteristics.

Patients receiving midazolam did not differ significantly from those receiving propofol regarding age, gender, indication for sedation, ASA-classification DMV-score and vital parameters prior to sedation. However, they received supplemental oxygen during the sedation less frequently (41 vs. 87%, $p < 0.001$), and were administered opioid analgesics prior to- or during procedural sedation more frequently (91% vs. 78%, $p < 0.001$).

4.2. Sedation efficacy

Procedures under propofol sedation were more often described as successful by the treating physician then procedures under midazolam sedation (92% vs. 82%, $p < 0.001$). Patients sedated with propofol were more frequently totally or deeply sedated, whereas patients receiving midazolam were more often moderately or lightly sedated (Table 3). Duration of sedation with propofol was significantly shorter compared to sedation with midazolam (10 min vs. 17 min, $p < 0.001$).

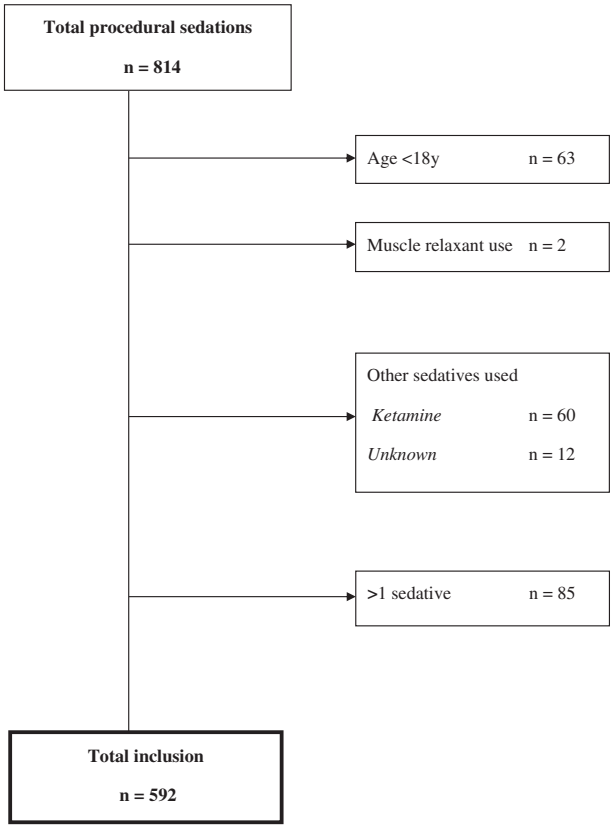

Fig. 1. Patient inclusion.

4.3. Sedation (adverse) events

No sedation adverse events occurred in our study population. A total of 112 sedation events were registered for 99 patients. Of all sedation events, apnea occurred most often (n = 73), followed by oxygen desaturation < 90% (n = 18), airway obstruction responsive to simple maneuvers (n = 13), and hypotension (n = 6), Table 3. As expected, sedation depth was directly related to the occurrence of apnea in our study population: 6 out of 218 patients (3%) who were described to be lightly- or moderately sedated had a transient apnea vs. 55 out of 160 patients (34%) who were deeply- or totally sedated, $p < 0.001$. This relation was independent of the sedative used.

PSA with propofol was associated with a higher total number of sedation events (n = 64, 23%) compared to procedural sedation with midazolam (n = 35, 11%), $p < 0.001$. This was almost completely attributable to the higher incidence of transient apnea's (55 (20%) vs. 18 (10%), $p = 0.004$). In 52 out of 55 patients with an apnea after propofol sedation, the apnea resolved after a brief vocal or tactile stimulus. Four patients sedated with propofol (1%) had an oxygen desaturations < 90% for >60 s. Bag-valve-mask (BVM) ventilation was applied in these patients as it was in 6 other patients with transient hypoventilation who did not fulfil the criteria for clinically relevant oxygen desaturation. None of these patients needed advanced airway interventions or hospitalization.

Clinically relevant oxygen desaturations < 90% as a result of hypoventilation was seen more often in patients sedated with midazolam (n = 14, 8%). This could not (only) be explained by the finding that these patients received more often opioid co-medication and less often oxygen supplementation during their sedation, since no significant interactions were found for these factors in loglinear analysis. BMV ventilation was applied in two patients, whereas in the remainder additional oxygen was supplied by non-rebreathing mask or nasal cannula. In three patients a benzodiazepine antagonist (Flumazenil) was administered to reverse the sedative effect of midazolam. None of the patients needed advanced airway interventions or hospitalization.

5. Discussion

In the present study we compared effectiveness and safety of propofol and midazolam for procedural sedation in the ED. We found that sedation with either of the agents is associated with a high procedure success rate. Procedure success rates for propofol sedations (92%) were comparable to previous reports on propofol sedations, [14] and were higher than for midazolam sedations (82%). This might be related to the deeper levels of sedation that were reached with propofol compared to midazolam. Midazolam sedations were longer in duration than propofol sedations. This is accordance with previous publications, in which procedural sedation with propofol was associated with clinically relevant shorter sedation times compared to procedural sedation with midazolam [7,9-11]. Although we did not measure time to discharge in our current study (since this was not recorded on the sedation registry forms), previous studies have demonstrated that patients sedated with propofol for procedures in the ED could be discharged from the ED up to 40 min earlier compared to patients receiving midazolam for PSA [8-10]. This is something to consider in the current era of ED-crowding.

In line with previous studies that demonstrated the safety of propofol and midazolam for procedural sedation, no sedation adverse events such as aspiration, laryngospasm, need for intubation, hospital admission or death, occurred in our study population. This is in accordance with current literature, wherein adverse events during

Table 2
Patient characteristics stratified by sedative used.

	All	Propofol	Midazolam	p*	Missing
Patients	592	284 (48%)	308 (52%)		
Indication					1
Hip dislocation	283 (48%)	127 (45%)	156 (51%)	ns	
Other dislocation	173 (29%)	75 (26%)	98 (32%)	ns	
Fracture reduction	71 (12%)	33 (12%)	38 (12%)	ns	
Abscess drainage	36 (6%)	33 (12%)	3 (1%)	<0.001	
Other	28 (5%)	16 (6%)	12 (4%)	ns	
Biometrics					
Age (y)	68 (47–78)	69 (46–80)	67 (48–76)	ns	16
Gender (male)	267 (45%)	122 (43%)	144 (47%)	ns	7
Co-morbidity					
ASA-class					13
I	252 (43%)	113 (40%)	139 (45%)	ns	
II	275 (46%)	138 (49%)	137 (45%)	ns	
III	50 (10%)	26 (9%)	24 (8%)	ns	
IV	2 (0%)	2 (1%)	0	ns	
DMV score ≥ 2	155 (26%)	82 (29%)	73 (24%)	ns	123
Weight (kg)	80 (70–90)	78 (70–87)	80 (70–90)	ns	66
Medication use					64
Anti-hypertensive	166 (28%)	91 (32%)	75 (24%)	ns	
Beta blocking drugs	75 (13%)	46 (16%)	29 (9%)	ns	
Other	91(15%)	45 (16%)	46 (15%)	ns	
Inhalation medication	19 (3%)	11 (4%)	8 (3%)	ns	
Immunosuppressant	22 (4%)	15 (5%)	7 (2%)	ns	
Hours fasting					
Liquids	4 (3–5)	4 (3–6)	4 (2–5)	ns	
Food	5 (3–7)	5 (3–8)	4 (3–6)	ns	
Vitals pre-sedation					
SBP (mm Hg)	145 (130–163)	150 (133–166)	137 (125–154)	ns	263
HR (bpm)	78 (69–90)	76 (69–90)	80 (70–86)	ns	
RR (rpm)	15 (12–18)	15 (12–18)	14 (12–16)	ns	260
Oxygen saturation (%)	100 (99–100)	100 (100−100)	99 (97–100)	ns	236
Co-administration opioid	503 (94%)	222 (78%)	281 (91%)	<0.001	57
Fentanyl	460 (77%)	201 (70%)	259 (84%)	<0.001	
Morphine	22 (4%)	14 (5%)	8 (3%)	ns	
Piritramide	21 (4%)	7 (2%)	14 (5%)	ns	
Oxygen during sedation	372 (63%)	246 (87%)	126 (41%)	<0.001	190

Data represented as n (%) and median (IQR). ASA-class = American Society of Anaesthesiologists classification; DMV score = difficult mask ventilation score; SBP, systolic blood pressure; RR, respiratory rate; HR, heart rate; ns., not significant.
* Missing data are excluded from analysis.

procedural sedation in the ED are reported to be exceedingly rare [2]. However, it should be stressed that the number of sedations in our study might have been too small to encounter one or more of these (rare) adverse events, and therefore the safety profile of propofol for ED sedations should not be overestimated. Although adverse events are rare, they can occur, and anyone providing procedural sedation should anticipate on their occurrence and be prepared to intervene when necessary.

Transient apnea was the most prevalent encountered sedation event, occurring in 10% of the patients sedated with midazolam and 20% of the patients sedated with propofol. This is comparable to prevalence reported in previous reports on ED propofol sedations [15-17]. Apneas seldom resulted in oxygen desaturations when patients were sedated with propofol. This can be explained by the fact that our population consisted to a large extend of relatively healthy ASA I-II population. Furthermore, pre-oxygenation was a standard procedure, and oxygen supplementation during the sedation procedure was provided in many patients. Finally, since apnea was defined as the absence of spontaneous breath for as short as 20 s, significant oxygen desaturation was not to be expected for most subjects from a physiological perspective. Although apnea occurred less frequently in patients sedated with midazolam, clinically relevant oxygen desaturations < 90% was seen more often in these patients. As we demonstrated, this could not be attributed to the finding that they more often received opioid co-medication or less often oxygen supplementation during their sedation. Persistent bradypnea (due to the longer half-life of midazolam compared to propofol) as opposed to a short apnea after propofol sedation might be one of the explaining factors. End tidal CO_2 monitoring might help detect the bradypnea before clinical significant oxygen desaturation occurs [18]. However, this was not standard monitoring in our study population.

It should be stressed that our findings should not be generalized to individual patients: Careful consideration of indication (duration- and required depth of sedation), co-morbidities, allergies and findings on physical exam remains warranted in order to choose the most suitable sedative agent for each individual patient. Furthermore, it should be noted that procedure success rate and sedation event incidence are not only dependent on the choice of sedative. Many factors (including monitoring, experience of sedationist and proceduralist, and hospital resources) play a role, and should be taken into account.

6. Limitations

Our study has several limitations, most being inherent to the retrospective design. First, we had to cope with missing data. Although a standardized template was used, sedation registration forms were often incomplete. We cannot exclude that these missing data could have contributed to any between group-differences, or could have modified our loglinear analyses. While age, gender, body weight, ASA-classification, fasting state, vital parameters and medication use were not different between the propofol and the midazolam group, we cannot be sure that the sedation risk as assessed by the treating physician might have influenced the choice of sedative. The choice of sedative in our study was at least also influenced by local preferences: Propofol was used as the predominant sedative in two centers, whereas midazolam was the predominant sedative in two other centers. Furthermore,

Table 3
Sedation characteristics, efficacy and (adverse) events.

	All	Propofol	Midazolam	p*	Missing
Total dose (mg)		75 (50–110)	4 (2,5–5)		21
Sedation depth					111
Total	25 (5%)	18 (8%)	7 (3%)	0.03	
Deep	168 (35%)	109 (45%)	59 (25%)	<0.001	
Moderate	210 (44%)	85 (35%)	125 (52%)	<0.001	
Light	77 (16%)	29 (12%)	48 (20%)	0.02	
Duration of sedation (min)	12 (10–17)	10 (8–15)	17 (12–26)	<0.001	371
Successful procedure	510 (86%)	257 (92%)	248 (81%)	<0.001	8
Sedation events					
One or more events	99 (17%)	64 (23%)	35 (11%)	<0.001	3
Agitation	1 (0%)	1	0	ns	
Vomiting	1 (0%)	0	1	ns	
Airway obstruction	13 (3%)	7 (3%)	6 (4%)	ns	
Apnea > 20 s	73 (16%)	55 (20%)	18 (10%)	0.004	
Sat < 90% > 30 s	18 (4%)	4 (1%)	14 (8%)	0.001	
SBP < 90	6 (1%)	3 (1%)	3 (2%)	ns	
Sedation *adverse* events					
Aspiration	0	0	0		
Laryngospasm	0	0	0		
Intubation	0	0	0		
Hospitalization	0	0	0		
Mortality	0	0	0		
Interventions (% of total sedation events)	61 (62%)	39 (61%)	22 (66%)		26
None	12 (12%)	11 (17%)	1 (3%)	0.06	
Vocal or tactile stimulus	24 (24%)	15 (23%)	9 (26%)	ns	
Airway maneuver	15 (15%)	13 (20%)	2(6%)	ns	
BMV ventilation	12 (12%)	10 (16%)	2 (6%)	ns	
Fluid bolus	2 (2%)	1 (2%)	1 (3%)	ns	
Antagonist administration**	3 (3%)	0	3 (9%)	0.03	

Data represented as n (%) and median (IQR). n.s. = not significant; SBP, systolic blood pressure; BMV = bag mask valve.
* Missing data are excluded for analysis.
** Antagonist administration = either Naloxone or Flumazenil or both, statistics performed with Fisher exact test.

procedural sedation registration using the Netherlands Society of Emergency Medicine (NSEP) template did not start in all hospitals at the same time. As a result, over/under representation of certain centers (with their local sedation preferences and/or experience in providing procedural sedation) might have influenced the cross-sectional character of the study. Finally, our results cannot be generalized to other populations and other departments/other situations wherein procedural sedation is administered: our population consisted mainly of ASA I and II subjects, and sedations were carried out by emergency physicians who had received dedicated training to do so.

7. Conclusion

Propofol is more effective and at least as safe as midazolam for procedural sedation in the ED.

Supplementary data to this article can be found online at http://dx.doi.org/10.1016/j.ajem.2016.12.075.

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