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Citation for published version (APA):

Smits, G. J. P., Kuypers, M. I., Mignot, L. A. A., Reijners, E. P. J., Oskam, E., van Doorn, K., Thijssen, W. A. M. H., & Korsten, E. H. M. (2017). Procedural sedation in the emergency department by Dutch emergency physicians: A prospective multicentre observational study of 1711 adults. *Emergency Medicine Journal (EMJ)*, 34(4), 237-242. <https://doi.org/10.1136/emered-2016-205767>

DOI:

[10.1136/emered-2016-205767](https://doi.org/10.1136/emered-2016-205767)

Document status and date:

Published: 01/04/2017

Document Version:

Publisher's PDF, also known as Version of Record (includes final page, issue and volume numbers)

Please check the document version of this publication:

- A submitted manuscript is the version of the article upon submission and before peer-review. There can be important differences between the submitted version and the official published version of record. People interested in the research are advised to contact the author for the final version of the publication, or visit the DOI to the publisher's website.
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- The final published version features the final layout of the paper including the volume, issue and page numbers.

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Procedural sedation in the emergency department by Dutch emergency physicians: a prospective multicentre observational study of 1711 adults

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► Additional material is published online only. To view please visit the journal online (<http://dx.doi.org/10.1136/emmermed-2016-205767>).

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Received 5 February 2016
Revised 27 September 2016
Accepted 2 October 2016
Published Online First
21 October 2016

ABSTRACT

Objective To describe our experience performing ED procedural sedation in a country where emergency medicine (EM) is a relatively new specialty.

Methods This is a prospective observational study of adult patients undergoing procedural sedation by emergency physicians (EPs) or EM residents in eight hospitals in the Netherlands. Data were collected on a standardised form, including patient characteristics, sedative and analgesic used, procedural success, adverse events (classified according to World SIVA) and rescue interventions.

Results 1711 adult cases were included from 2006 to 2013. Propofol, midazolam and esketamine (S+ enantiomer of ketamine) were the most used sedatives (63%, 29% and 8%). We had adverse event data on all patients. The overall adverse event rate was 11%, mostly hypoxia or apnoea. There was no difference in adverse event rate between EPs and EM residents. However, there was a significantly higher success rate of the procedure when EPs did the procedural sedation (92% vs 84%). No moderate (unplanned hospital admission or escalation of care) or sentinel SIVA outcomes occurred (pulmonary aspiration syndrome, death or permanent neurological deficit).

Conclusion Adverse events during procedural sedation occurred in 11% of patients. There were no moderate or sentinel outcomes. All events could be managed by the sedating physician. In a country where EM is a relatively new specialty, procedural sedation appears to be safe when performed by EPs or trained EM residents and has comparable adverse event rates to international studies.

INTRODUCTION

Procedural sedation and analgesia (PSA) is an essential technique that enables emergency physicians (EPs) to perform painful procedures in a humane and timely manner within the ED. However, without proper physician and nurse training, vital signs monitoring and quality assurance, sedation can lead to serious adverse events. In 1995, Quine reported a mortality of 1 in 2000 sedated patients for gastroscopy in the UK and found that only 40% of patients had oxygen saturation monitoring during the procedure.¹ Since then multiple studies have shown that procedural sedation is safe, and deaths are very infrequent when it is done in concordance with current procedural sedation guidelines.^{2–4}

The emergency medicine (EM) training programme in the Netherlands was officially recognised by the Medical Specialist Registration

Key messages

What is already known on this subject?

- Procedural sedation is safe when performed by emergency physicians.
- The use of propofol for ED sedation by emergency medicine doctors is not well accepted by some non-emergency medicine specialties in some countries.

What this study adds?

- Procedural sedation is safe in the hands of emergency physicians and residents in a country where emergency medicine is a relatively new specialty.
- Our findings suggest that the safety profile of propofol is similar to that of midazolam. However, sedation was more often successful with the use of propofol.

Committee of the Royal Dutch Society for Medicine in 2008 and as such is still a very young specialty in the Netherlands. The first 3-year EM training programmes in the Netherlands started in 2000 in four hospitals spread over the country. Prior to this, and to some extent till today, the EDs were mostly staffed by recent medical school graduates, often working only with distant supervision by telephone by a non-EM specialist.⁵ Most inter-nists, orthopaedists, surgeons and non-ED residents are not trained in PSA and rely on the anaesthesiologists who are usually not readily available in the ED and are not comfortable with sedating non-fasted patients.⁶ As a result, procedures are either performed in the ED without adequate analgesia and sedation or have to go to the operating theatre, which leads to prolonged waiting times and increased expenditure.⁷

Two of the early adaptors of Dutch ED training programmes (the OLVG and Albert Schweitzer hospital) invited US trained physicians to serve as residency directors and help train their residents. During this time procedural sedation was introduced.⁶ In another hospital (St. Elisabeth Hospital, Tilburg), PSA was introduced to the EM physicians by an anaesthesiologist. Since then its use has spread. In 2012, the Netherlands Society of Emergency Physicians (NSEP) launched a national EM PSA course for EPs, following the guidelines of the Dutch Institute for Healthcare Improvement.⁴



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To cite: Smits GJP, Kuypers MI, Mignot LAA, et al. *Emerg Med J* 2017;**34**:237–242.

Aside from contributing to the world's literature on safety of PSA by EPs, it is important to assess its safety in a country where EM is a relatively new specialty. We included all used sedatives to reflect the practice in our country.

The aim of this multicentre study was to assess the safety of ED procedural sedation by Dutch EM physicians and EM residents.

METHODS

Study design and setting

This is a prospective observational study of adult patients undergoing procedural sedation by EPs or EM residents in eight hospitals in the Netherlands (seven community hospitals (of which six are EM teaching hospitals) and one academic medical centre) from 2006 to 2013. Not all hospitals contributed data for the whole period (2006–2013) because PSA was not introduced at the same time. The annual census of these hospitals ranged from 14,490 to 41,586 ED visits. The study was approved by the nationally recognised Institutional Review Board of the Catharina hospital Eindhoven and this decision was adopted by the other participating centres.

Selection of participants

Patients aged 17 and older were included if they received PSA in the ED by a qualified EP consultant or EM resident. Dutch EM residents all have airway management training in their first months of training and have to perform supervised PSAs until deemed competent to perform it unsupervised. Only American Society of Anesthesiologists (ASA) class I–III patients were eligible for PSA by non-anaesthesiologists in keeping with the 1998 national consensus guidelines.⁸ Patients were excluded if sedation was needed to treat agitation or psychosis or if sedation was needed for intubation or mechanical ventilation. Fasting state was not an exclusion criterion.

Interventions

A preprocedural screening was performed using a standardised PSA registration form. Information recorded included ASA classification, medical history, allergies, height and weight, expected airway difficulties and fasting state. Vitals signs were measured at regular intervals, during and after the procedure, until the patient was fully awake. The measurements included BP, RR, pulse oximetry and HR. ECG monitoring was included in most patients as well. Except for one hospital, end-tidal CO₂ monitoring was not used since it has only been recently introduced in the Dutch setting. Depth of sedation was registered using ASA levels of sedation for non-esketamine sedations. One hospital used Ramsay scale instead of ASA.⁹ When esketamine (the S+ enantiomer of ketamine) was used, the dissociative state was registered (yes/no). Airway equipment was available in the room, and full resuscitation equipment readily available in the department. The patients received a sedative and analgesic depending on the local ED protocol.

After the PSA, the physicians registered the deepest level of sedation, amnesia, pain ratings with the verbal numerical rating scale (VNRS-11; 0=no pain to 10=worst imaginable pain),¹⁰ duration of PSA (from administration of the sedative until the discharge criteria were met) and successful completion of the procedure for which the PSA was required. The discharge criteria were level of consciousness as before sedation, able to eat and drink, no nausea, pain well under control, vital signs stable (breathing, circulation), and a minimum of 2 hours after administration of a reversal agent.

Methods and measurements

Data were registered using a procedural sedation form, based on the template of the Netherlands Society of Emergency Physicians (see online supplementary file 1). Additionally, all participating centres were queried for events related to procedural sedation in the ED through their hospital adverse incidents databases.

Outcomes

The primary outcome was the number of adverse events, defined as: airway obstruction, apnoea (>20 s), hypoxia (oxygen saturation <90% for >60 s), hypotension (systolic BP <90 mm Hg), bradycardia (<50/min), agitation, aspiration, hospital admission due to PSA, or other.

To classify the interventions and outcomes after an adverse event, the World SIVA adverse sedation reporting tool was applied in retrospect.¹¹

SIVA interventions

These are classified as minimal (no intervention, additional sedatives, antiemetics or antihistamines), minor (airway repositioning, tactile stimulation, supplemental oxygen or antisialagogue), moderate (bag valve mask ventilation, laryngeal mask, oral/nasal airway, continuous positive airway pressure, reversal agents, rapid intravenous fluids or intravenous anticonvulsant) and sentinel (cardiopulmonary resuscitation, tracheal intubation, neuromuscular block, pressor/epinephrine or atropine to treat bradycardia).

SIVA outcomes

These are classified as minimal (no adverse outcome), moderate (unplanned hospital admission or escalation of care) and sentinel (pulmonary aspiration syndrome, death or permanent neurological deficit).

Secondary outcomes were success of the procedure and amnesia.

Post hoc, we investigated the influence of seniority (EP vs EM resident) on adverse events rate, procedural success rate and choice of sedative.

Analysis

Data were analysed with SPSS V.19. Continuous variables were presented as means (95% CIs) or medians (IQR; min–max) depending on normal distribution of the data. Categorical variables were presented as percentages. We used the modified Wald method (Agresti and Coull) to calculate 95% CI of proportions, and the Wilson method (without continuity correction) for 95% CI for difference between proportions. A Kruskal-Wallis H test, followed by a Mann-Whitney U test with Bonferroni correction, was used for testing continuous variables per sedative (duration of sedation). A χ^2 test was used for significance of categorical data (adverse events, success of the procedure, amnesia, level of training, age groups, oxygen use, level of sedation). A Mann-Whitney U test was used for calculating significance for sedative dosing in age groups and level of training. A logistic analysis was used for testing association between patient age and adverse events. A *p* value less than 0.05 was considered statistically significant.

RESULTS

Characteristics of study subjects

The analysis included 1711 patients (17 patients were excluded due to unrecorded patient age). Patient characteristics are described in table 1. The median age was 59 years (min–max 17–100 years), with 41.8% aged 65 and older. More than half had an ASA class of I.

Table 1 Characteristics of patients undergoing procedural sedation in the ED (n=1711)

	n*	
Median age, years (IQR)	1711	59 (41–77)
Men, %	1709	46.0
Median body weight, kg (IQR)	1602	75 (65.5–84.5)
ASA class, %	1699	
I		53.3
II		40.0
III		6.7
Fasting in hours, %	1311	
0–3		19.0
3–6		44.4
>6		36.6

*Due to missing data, this is the total number of cases included in the analysis of this variable.

ASA, American Society of Anesthesiologists.

Main results

The most frequent indications for PSA were dislocations of the hip and shoulder (29.2% and 26.1%; online supplementary table S1).

Propofol and midazolam were the most commonly used sedatives with an average dose of 1.1 and 0.06 mg/kg, respectively (table 2). In the majority of the non-esketamine cases, an opioid was added before giving the sedative (85.3%).

Propofol was associated with a significant shorter duration of sedation ($p<0.001$) when compared with esketamine or midazolam (table 2).

ASA sedation depth was registered in only 985 of 1315 patients (table 4), with 36.7% being deeply sedated or higher. In the one hospital that used the Ramsay sedation scale, sedation depth was registered in 206 of 267 cases, with 38.9% having a scale of 4 or 5 (brisk or sluggish response to a light glabellar tap or to verbal stimulus) and no one with a scale of 6 (no response). Dissociation scoring was registered in 71 of 129 esketamine cases with 77.5% of 71 patients being dissociated.

Adverse events

There were a total of 194 adverse events involving 181 of 1711 patients (10.6%; table 3), most frequently hypoxia (4.0%) and

apnoea (2.9%). Bag valve mask ventilation and airway repositioning were performed in 2.6% and 2.0%, respectively. All events were successfully treated by the sedating physician. There were no sentinel interventions, moderate or sentinel outcomes as a result of the PSA. The majority of patients (74.6% of 1458) received supplemental oxygen, and there was however no significant difference in adverse events (supplemental oxygen 10.1%, no oxygen 13.8%; difference 3.7% (95% CI 0.0% to 7.9%); $p=0.051$).

There was no significant difference in percentage of adverse events between propofol, midazolam and esketamine ($p=0.88$; table 2). There was, however, an increasing frequency of adverse events with increasing age ($p<0.001$; figure 1) despite statistically significant lower total sedative dosing in patients aged 65 and over (median dose mg/kg (IQR) propofol 0.9 (0.6–1.3) vs 1.3 (0.8–1.8) $p<0.001$; midazolam 0.04 (0.03–0.06) vs 0.05 (0.03–0.08) $p=0.025$; esketamine 0.4 (0.3–0.5) vs 0.5 (0.4–0.6) $p<0.001$).

Propofol had a higher adverse event rate in patients aged 65 and over (17.0% vs 7.1%; difference 9.9%; 95% CI 5.9% to 14.3%; $p<0.001$). This was not significant for midazolam (13.0% vs 7.9%; difference 5.1%; 95% CI –0.5% to 10.4%; $p=0.07$).

No additional events or incidents were found in the hospitals' adverse incident reporting systems.

Success of procedure and amnesia

The procedures could be successfully completed with PSA in 90.1% of cases.

Propofol was associated with a significant higher procedural success rate than midazolam (93.1% vs 84.1%; difference 9.1%; 95% CI 5.7% to 12.9%; $p<0.001$) and esketamine (88%; difference 5.2%; 95% CI 0.2% to 12.1%; $p<0.001$; table 2). There was no statistically significant association between dosage and procedural success rate.

In 83.4% of patients there was amnesia to the procedure (table 2). With esketamine, there was significantly more amnesia than with midazolam (difference 11.7%; 95% CI 0.6% to 20.0%; $p=0.38$), but not compared with propofol (difference 6.6%; 95% CI –3.5% to 12.5%; $p=0.17$).

As expected, there was an increase of amnesia with increasing sedation levels (table 4). Minimal and moderate levels had significantly less amnesia than deep or general anaesthesia (75.8%

Table 2 Sedatives used in patients undergoing procedural sedation in the ED (n=1711*)

	Propofol n=1074		Midazolam n=499		Esketamine n=129	
	n†		n†		n†	
Median age (IQR)	1074	55.5 (38–73)	499	69 (54–84)	129	48 (32.5–63.5)
Median total dose, mg/kg (IQR)	942	1.1 (0.7–1.6)	413	0.06 (0.04–0.08)	108	0.5 (0.3–0.6)
Median sedation duration, minutes (IQR)	631	15 (11–19)	175	25 (12.5–37.5)	40	25 (16–34)
ASA sedation deep or higher‡, % (95% CI)	691	43.1 (39.5 to 46.9)	288	21.5 (17.2 to 26.6)	71	77.5 (66.5 to 85.6)‡
Opioid coanalgesia, % (95% CI)	1074	84.2 (81.9 to 86.2)	499	87.6 (84.4 to 90.2)	129	12.4 (7.8 to 19.2)
Esketamine coanalgesia, % (95% CI)	1074	2.0 (1.4 to 3.1)	499	0 (0 to 0.8)	129	0 (0 to 3.9)
Adverse events, % (95% CI)	1074	10.7 (9.0 to 12.7)	499	10.8 (8.4 to 13.9)	129	9.3 (5.3 to 15.7)
Amnesia, % (95% CI)	677	83.9 (80.9 to 86.5)	179	78.8 (72.2 to 84.2)	63	90.5 (80.4 to 95.9)
Success of procedure, % (95% CI)	1051	93.1 (91.5 to 94.5)	483	84.1 (80.5 to 87.1)	125	88.0 (81.0 to 92.7)

*Nine cases received other sedatives: etomidate (2), diazepam (1), other (1), missing (5); due to low numbers, these were not included in this table.

†Due to missing data, this is the total number of cases included in the analysis of this variable (denominator).

‡For esketamine: proportion of dissociated patients (instead of ASA levels of sedation).

ASA, American Society of Anesthesiologists.

Table 3 Adverse events with their interventions in patients undergoing procedural sedation in the ED (n=1711)

	Adverse events, n (%)
Minimal intervention*	
Agitation	6 (0.4)
Emesis	5 (0.3)
Emergence phenomena	3 (0.2)
Hypotension—no intervention	7 (0.4)
Hypoxia—no intervention	1 (0.1)
Tachycardia	1 (0.1)
Other: subcutaneous injection of sedative (n=1), unknown (n=1)	2 (0.1)
Total minimal intervention	25 (1.5)
Minor intervention*	
Airway obstruction—stimulate	3 (0.2)
Airway obstruction—airway repositioning	27 (1.6)
Apnoea—stimulate	23 (1.3)
Hypoxia—stimulate	13 (0.8)
Hypoxia—airway repositioning	8 (0.5)
Hypoxia—oxygen administration	25 (1.5)
Total minor intervention	99 (5.8)
Moderate interventions*	
Airway obstruction—oral airway insertion	2 (0.1)
Apnoea—bag valve mask ventilation	25 (1.5)
Apnoea—reversal agent administration	2 (0.1)
Hypotension—fluid bolus	20 (1.2)
Hypoxia—bag valve mask ventilation	19 (1.1)
Hypoxia—reversal agent administration	2 (0.1)
Total moderate intervention	70 (4.1)
Sentinel interventions	0 (0)
Total number of adverse events	194 (11.3)
Total number of cases with adverse events†	181 (10.6)

*Interventions classified according to World SIVA adverse sedation reporting tool 2012.

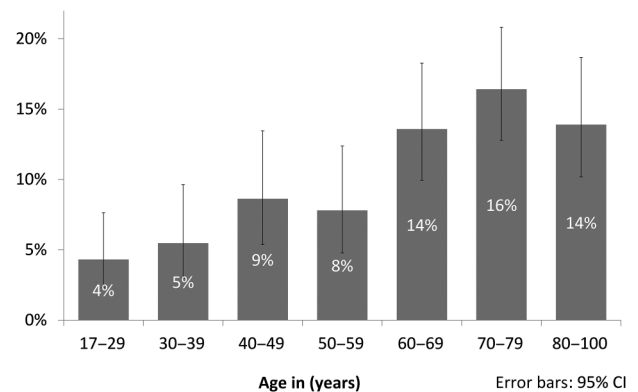
†Some patients had more than one adverse event.

vs 92.9%; difference 17.1%; 95% CI 12.1% to 21.9%; $p < 0.001$).

Level of training

The majority of patients (79.7%) were sedated by an EP, and the remainder by an EM resident.

EPs used propofol and esketamine more frequently than EM residents (table 5). The doses of the sedatives in mg/kg were the same. The percentage of adverse events was the same for EP

**Figure 1** Patients with adverse events per age group during procedural sedation in the ED (n=1711).

and EM residents. However, EPs had a significantly higher overall success rate of the procedure than residents (table 5).

DISCUSSION

Adverse events rate

In this multicentre study of 1711 adults undergoing procedural sedation by EPs, we found adverse events in 10.6% of patients. There were no sentinel outcomes. There was no statistical difference in adverse event rate between propofol, midazolam and esketamine. In other studies, the adverse event rate for propofol versus midazolam was also similar or even lower,^{2 12-15} refuting the notion that propofol is not suitable for use by non-anaesthesiologists.

The adverse event rate in our Dutch multicentre study is comparable with the rate in other international studies (3.5%–29.5%).^{2 12 13 15-17} This confirms that EPs, including EM residents, can safely perform PSA in a country with a relatively new EM training programme. We found no difference in adverse event rate between EPs and EM residents. Similar rate of adverse events in EM residents suggests that this was a safe practice. Since 2015 PSA training is part of the core curriculum of the EM training programme.

Increasing age was significantly associated with increasing adverse events in our study, despite the fact that they received significantly lower sedative doses. Increased adverse event rate with age is found in some studies, but not all.^{13 18}

Success of the procedure

Our overall procedural success rate of 90% is not as high as other studies (95%–96%); however, this may be partly due to a higher rate of hip reductions in our study, a procedure known

Table 4 Sedation level* and amnesia in patients undergoing procedural sedation in the ED (n=1711)

ASA levels of sedation	Total		Amnesia	
	nt	% (95% CI)	nt	% (95% CI)
Minimal	158	16.0 (13.9 to 18.5)	105	47.6 (38.3 to 57.1)
Moderate	465	47.2 (44.1 to 50.3)	341	84.5 (80.2 to 87.9)
Deep	343	34.8 (31.9 to 37.9)	293	92.8 (89.3 to 95.3)
General anaesthesia	19	1.9 (1.2 to 3.0)	17	94.1 (73.0 to 99.0)
Total	985	100	756	82.8 (80.0 to 85.3)

*Patients with missing data, Ramsay sedation scale or ketamine dissociation scale (n=49) not included in this table.

†Due to missing data, this is the total number of cases included in analysis of this variable (denominator).

ASA, American Society of Anesthesiologists.

Table 5 Level of training and outcomes in patients undergoing procedural sedation in the ED (n=1711)

	EP, n=1364 n*		EM resident, n=347 n*		Significance
Propofol used, n (%)	887	887 (65.0)	187	187 (53.9)	
Median dose, mg/kg (IQR)	818	1.1 (0.7–1.6)	124	1.0 (0.5–1.5)	p=0.35
Success of procedure, % (95% CI)	866	94.3 (92.6 to 95.7)	185	87.6 (82.0 to 91.6)	p<0.001
Midazolam used, n (%)	345	345 (25.3)	154	154 (44.4)	
Median dose, mg/kg (IQR)	275	0.04 (0.02–0.06)	138	0.05 (0.03–0.07)	p=0.16
Success of procedure, % (95% CI)	337	86.1 (81.9 to 89.4)	146	79.5 (72.1 to 85.3)	p=0.07
Esketamine used, n (%)	124	124 (9.1)	5	5 (1.4)	
Median dose, mg/kg (IQR)	107	0.46 (0.3–0.6)	†	†	
Success of procedure, % (95% CI)	120	87.5 (80.3 to 92.4)	†	†	
Other sedatives used, n (%)	8	8 (0.6)	1	1 (0.3)	
Success of procedure, % (95% CI)	1331	91.7 (90.1 to 93.0)	337	84.0 (79.7 to 87.5)	p<0.001
Adverse events, % of cases (95% CI)	347	10.5 (9.0 to 12.2)	1364	11.0 (8.1 to 14.7)	p=0.8

*Due to missing data, this is the total number of cases included in analysis of this variable (denominator).

†Only five cases.

EM, emergency medicine; EP, emergency physician.

to have higher failure rates.^{2 19} Excluding all hip reductions in our study would increase the success rate to 93%. Relative inexperience with the procedure itself for which PSA was indicated might also have contributed.

We found a 7.7% absolute difference in success rate in favour of EPs compared with EM residents. This is not explained by sedative dosing, since this was similar in EPs and EM residents. Possibly when PSAs were done by EM residents they were assisted by a junior doctor (EM or specialty resident) to perform the indicated procedure.

In our study, propofol was associated with better procedural success rates than midazolam (even when corrected for the higher number of hip reductions in the midazolam group), which is similar to a study where 316 sedations in the ED were retrospectively analysed.¹⁴ In our study, patients receiving propofol had deeper levels of sedation than with midazolam, which may further explain its higher success rate.

Prudent midazolam dosing in our study (0.06 mg/kg) might have contributed to the lower success rates, as reported by Hohl *et al.*²⁰ Total dose of midazolam varies in the ED literature, from around 0.05 to 1.0 mg/kg or more.^{15 21–23} It is possible that the relatively high median age in our midazolam cohort (69 years) is a reason why such low doses were used.

Propofol and esketamine in our study had similar success rates, in contrary to an observational study from Australia, where ketamine had the highest rate.¹⁹

Amnesia

We found amnesia in 83% of patients, less than we would have expected. Likely this is due to the lower sedation levels in our cohort (ASA sedation level minimal 16%, moderate 47%), as we found lower sedation levels to be associated with less amnesia.

Limitations

We collected data from multiple centres, using mainly paper forms, which led to missing data for some variables such as ASA classification, body weight, sedation depth, success of procedure and amnesia. We however included all patients with missing data, except when the patients' age could not be found (to not accidentally include paediatric patients in our cohort).

During the study period, there was no mandatory registration of PSA by the NSEP. It is, therefore, possible that not all cases were registered. To find any occult serious adverse events, we, therefore, queried the hospitals' patient safety incident reporting databases, which showed no additional adverse events.

The variable amnesia was registered in only 54% of cases. Potentially the sedating doctor could have omitted to register amnesia if the patient was not amnesic. However, our amnesia rate of 83% is rather on the low side when compared with the literature. For example, recall of the procedure was found in 7.4% of 121 ER patients using propofol or midazolam²⁴ and 10% of 271 patients sedated with propofol or propofol/ketamine.¹⁷

In one hospital, sedation depth was not registered with ASA sedation levels, but with the Ramsey sedation score, which makes comparison more difficult. Furthermore, in the other hospitals ASA levels were only registered in 75% of patients. This reduced the number of patients in our analysis for sedation levels and has the potential to skew the results.

Since uniform reporting of adverse events only has been proposed in 2012,⁹ we only could retrospectively apply the World SIVA reporting tool. We applied this tool to the interventions needed and outcomes, not the adverse events themselves, since the tool used different cut-offs than ours.

CONCLUSION

In conclusion, procedural sedation—in a country where EM is a relatively new specialty—appears safe when performed by EPs and trained EM residents and has comparable adverse event rates as international studies, and resulted in no sentinel outcomes.

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Acknowledgements We thank the following hospitals for participating in the study: Catharina Hospital, Eindhoven; Maxima Medical Centre, Veldhoven; Meander

Hospital, Amersfoort, St. Elisabeth Hospital, Tilburg; Albert Schweitzer Hospital, Dordrecht/Zwijndrecht; Haga Hospital, Den Haag; Westfriesgasthuis, Hoorn and Radboud University Nijmegen Medical Centre, Nijmegen. We thank Saskia Houterman, PhD, epidemiologist, for reviewing the manuscript and statistical analysis; RTC Welsing, MD, emergency physician KNMG, Meander Medical Centre, Amersfoort; ATW Wei, MD, emergency consultant KNMG, Radboud University Medical Centre for providing data and Francis Mencl, MD, MS, FACEP, FAAEM, Summa Akron City hospital, Northeastern Ohio Medical University for reviewing the manuscript.

Contributors GJPS and MIK conceived the study and GJPS undertook recruitment of participating centres. GJPS, MIK, LAAM, EPJR, EO, KVD and WAMHT acquired the data. GJPS managed the data. MIK, WAMHT and EHMK helped with analysing and interpreting the data. GJPS drafted the manuscript. All authors contributed substantially to its revisions. GJPS takes responsibility for the paper as a whole.

Competing interests None.

Ethics approval Catharina Hospital Institutional Review Board.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement We also collected the variable 'difficulty of the procedure' (easy–normal–difficult) rated by the physician. This was filled in only 350 of 1711 cases. Available as SPSS file, by emailing the corresponding author.

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