Paediatric procedural sedation and analgesia by emergency physicians in a country with a recent establishment of emergency medicine

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Objectives **Paediatric patients receive less procedural sedation and analgesia (PSA) in the emergency department compared with adults, especially in countries where emergency medicine is at an early stage of development. The objectives of this study were to evaluate the adverse events and efficacy of paediatric PSA in a country with a recent establishment of emergency medicine and to describe which factors aided implementation.**

Methods **This is a prospective, multicentre, observational study of paediatric patients undergoing PSA by the first trained emergency physicians (EPs) in The Netherlands. A standardized data collection form was used at all participating hospitals to collect data on adverse events, amnesia, pain scores, and procedure completion. A survey was used to interpret which factors had aided PSA implementation.**

Results **We recorded 351 paediatric PSA. The mean age was 9.5 years (95% confidence interval: 9.1–10.0). Esketamine was most frequently used (42.4%), followed by propofol (34.7%). The adverse event rate was low (3.0%). Amnesia was present in 86.8%. The median pain score was 2 (out of 10) for patients without amnesia. Procedures were successfully completed in 93.9% of the cases.**

Conclusion **Paediatric PSA provided by the first EPs in The Netherlands showed appropriate levels of sedation and analgesia with a high rate of procedure completion and a low rate of adverse events. Our paper suggests that EPs provided with a proper infrastructure of mentorship, training and guidelines can implement effective paediatric PSA. *European Journal of Emergency Medicine* 26:168–173**

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Introduction

Worldwide, paediatric patients receive less procedural sedation and/or analgesia (PSA) in the emergency department (ED) when compared with adult patients [1–4]. 'Brutacaine', that is, the physical restraint of children during painful procedures is sadly still common practice in EDs [1–3]. Thus far, only countries with a long history of emergency medicine (EM), such as the USA and Australia, have developed paediatric PSA into a core competency of the emergency physician (EP). These countries have demonstrated that PSA can be applied safely and effectively by EPs, even in nonfasted paediatric patients, with agents like propofol and ketamine [5–11].

However, for countries with a more recent establishment of EM, it remains difficult to provide paediatric PSA in the ED. McCoy *et al.* [12] recently addressed the challenges of practice and provision of paediatric PSA in the UK and Ireland. The main findings were variability in practice, lack of formal training and a lack of recognition of PSA as a specialized EM skill [12]. When the first 3-year Dutch EM training programme started in 2000, similar challenges were anticipated. Hence, specific measures were taken to monitor and support the early realization of paediatric PSA by the first EPs [13]. These measures included inviting experienced EPs from other nations who were capable of training and coaching their peers, early implementation of PSA in the training programme and uniform registration.

The primary objective of this paper was to evalute the adverse event rate and efficacy of these first paediatric procedures of PSA performed by EPs and secondarily to describe how mentorship, guidelines, training and registration formed the cornerstones for success.

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Methods

Study design and setting

We performed a prospective observational data collection of paediatric patients undergoing PSA performed by EPs in eight Dutch teaching hospitals from 2006 to 2012. The annual census ranged from 14 490 to 41 586 ED visits. The hospitals were recruited once paediatric PSA by EPs had begun. The Institutional Review Board of the Catharina Hospital Eindhoven approved this study. The need for written informed consent and clinical trial registration were waived because there was no intent to change any patient's plan of care. The other participating centres adopted this decision.

Selection

We performed a consecutive sampling of all paediatric cases of PSA performed by an EP in the ED. All paediatric EM patients younger than 17 years receiving PSA were included. Patients were excluded if sedation was indicated for agitated delirium, psychosis or mechanical ventilation. Not all hospitals began with data collection simultaneously, as paediatric PSA was not introduced concurrently in all centres. A slow inclusion rate was expected because of the low number of EPs trained in paediatric PSA during the study period.

Implementation of procedural sedation and analgesia through mentorship

Over a period of 6 years, experienced EP consultants from other countries and/or anaesthesiologists with a special interest in EM-trained Dutch EPs by means of direct supervision in three teaching hospitals, this gradually advanced to the five other participating centres of this study. When PSA was introduced, it was performed in accordance with the national guideline [14]. Among other things, this included proper screening, monitoring and record keeping. Once the EP consultant deemed the local EPs qualified, they would perform the PSA procedure by themselves and began training other colleagues. The EPs usually started with adult PSA and with increasing experience progressed to younger patients. ED Nursing staff were trained concurrently in the assistance of PSA.

Procedure

A certified EP, who had completed the 3-year EM training programme and was competent in noninvasive airway management and Advanced Paediatric Life Support, set the indication for the PSA and performed the PSA. Initially this was performed under the supervision of foreign EPs or anaesthesiologists. The National consensus guideline for PSA was used as the standard reference [14]. Once informed consent for PSA and the procedure were obtained a preprocedural screening was performed. This included information on American Society of Anaesthesiologists (ASA) classification, medical history, allergies, height and weight, assessment of the airway and fasting state. The room where the sedation took place was equipped with a monitor for vital signs, ECG, oxygen, airway and resuscitation equipment. After analgesia was administered, the sedative was titrated to the appropriate level by the treating EP. Another physician performed the indicated procedure (e.g. fracture reduction). This enabled the EP to monitor the sedation and intervene if an airway, breathing or circulation problem occurred. A qualified ED-nurse monitored and noted the vital signs at 5-min intervals until the patient was fully awake and met the preset discharge criteria. Patients and/or their caregiver(s) were also given clear instructions to report back to the ED in case an unforeseen event occurred after discharge.

Measurements

Data were registered on a standardized PSA data collection form (Fig. 1) based on the template of the Netherlands Society of Emergency Physicians (NSEP) [15,16]. In addition, all participating centres were queried for events related to procedural sedation through their hospital adverse incidents' databases at the end of the study period.

Primary outcome

The primary outcome was performance of PSA by the EPs, measured by the (serious) adverse event rate and efficacy. Serious adverse events were defined as aspiration, intubation, cardiopulmonary resuscitation, permanent neurological deficit and death. Adverse events were defined as agitation, vomiting, airway obstruction, apnoea (>20 s), hypoxia (oxygen saturation $<90\%$ for >60 s) and hypotension or bradycardia (according to Advanced Paediatric Life Support guidelines). The adverse events, interventions and outcomes were retrospectively graded according to the World SIVA adverse sedation-event recording tool, as this grading tool was not available at the start of our study [17]. Efficacy of PSA was measured by amnesia or pain scores and successful procedure completion. The maximum pain score was rated in case there was no amnesia for the procedure. The verbal numerical rating scale (0–10) or Wong-Baker faces pain-rating scale (coded 0–10 with increments of 2) was used according to appropriate age [18]. A pain score of 3 or lower was considered adequate (no or little pain).

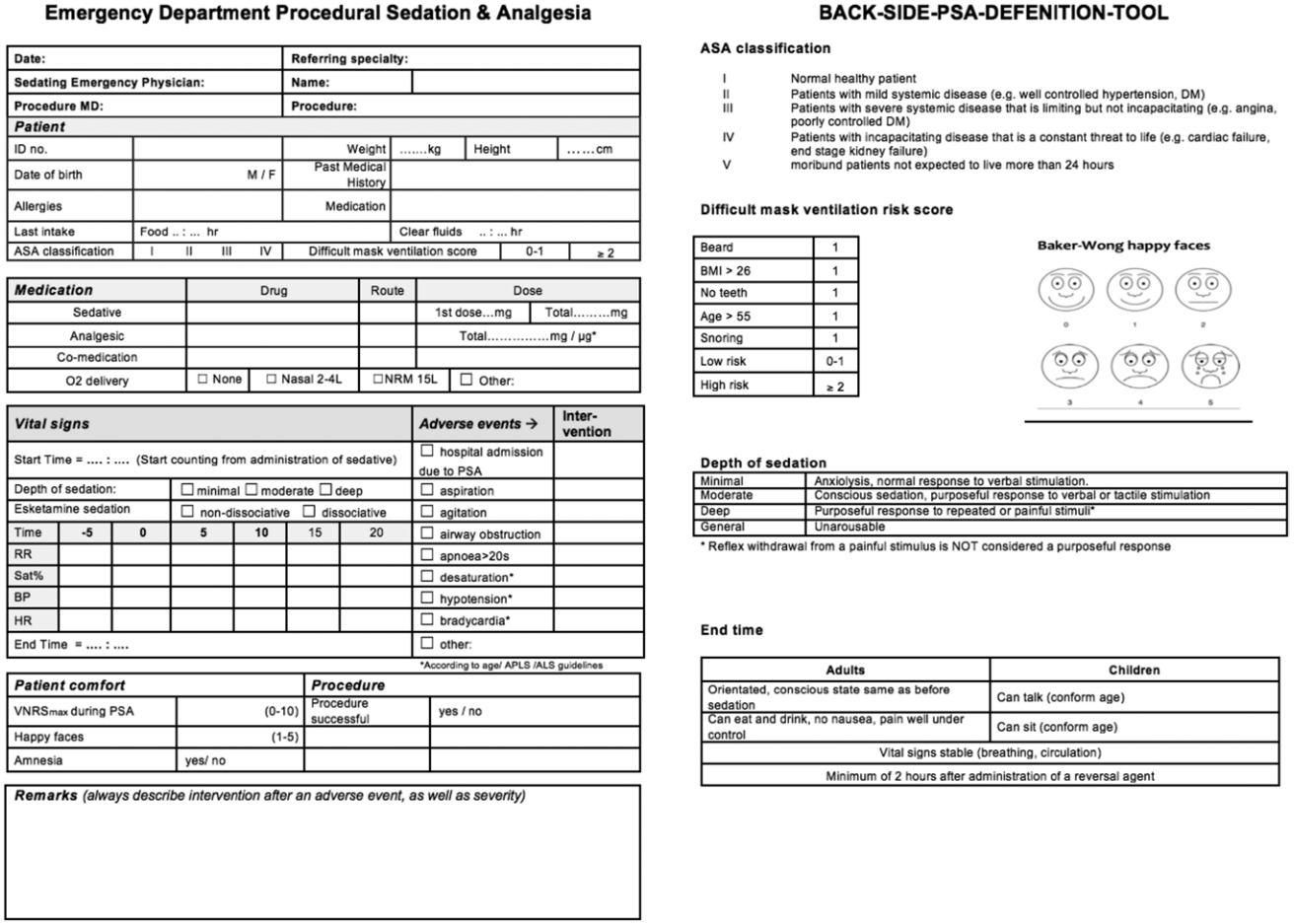
Secondary outcomes

The author group retrospectively evaluated the factors that helped implement paediatric PSA through an online survey. They were queried as to what degree certain factors had aided the implementation on a five-point Likert scale.

Statistical methods

Data were analysed using SPSS, v.23 (IBMCorp., Armonk, New York, USA). Continuous variables were presented as means [95% confidence intervals (CIs)] or medians

Fig. 1



Emergency Department Procedural Sedation & Analgesia

Date:		**Referring specialty:**			
Sedating Emergency Physician:		**Name:**			
Procedure MD:		**Procedure:**			
Patient					
ID no.		Weight	.....kg	Height	.....cm
Date of birth	M / F	Past Medical History			
Allergies		Medication			
Last intake	Food .. : ... hr		Clear fluids .. : ... hr		
ASA classification	I II III IV	Difficult mask ventilation score		0-1	≥ 2

Medication	Drug	Route	Dose	
Sedative			1st dose...mg	Total.....mg
Analgesic			Total.....mg / µg*	
Co-medication				
O2 delivery	☐ None ☐ Nasal 2-4L	☐NRM 15L	☐ Other:	

Vital signs							***Adverse events →***	**Inter-vention**
Start Time = ... : .... (Start counting from administration of sedative)							☐ hospital admission due to PSA	
Depth of sedation:	☐ minimal ☐ moderate ☐ deep						☐ aspiration	
Esketamine sedation	☐ non-dissociative ☐ dissociative						☐ agitation	
Time	-5	0	5	10	15	20	☐ airway obstruction	
RR							☐ apnoea>20s	
Sat%							☐ desaturation*	
BP							☐ hypotension*	
HR							☐ bradycardia*	
End Time = ... :							☐ other:	

*According to age/ APLS /ALS guidelines

Patient comfort		***Procedure***	
VNRS$_{max}$ during PSA	(0-10)	Procedure successful	yes / no
Happy faces	(1-5)		
Amnesia	yes/ no		

Remarks *(always describe intervention after an adverse event, as well as severity)*

BACK-SIDE-PSA-DEFENITION-TOOL

ASA classification

I	Normal healthy patient
II	Patients with mild systemic disease (e.g. well controlled hypertension, DM)
III	Patients with severe systemic disease that is limiting but not incapacitating (e.g. angina, poorly controlled DM)
IV	Patients with incapacitating disease that is a constant threat to life (e.g. cardiac failure, end stage kidney failure)
V	moribund patients not expected to live more than 24 hours

Difficult mask ventilation risk score

Beard	1
BMI > 26	1
No teeth	1
Age > 55	1
Snoring	1
Low risk	0-1
High risk	≥ 2

Baker-Wong happy faces

Depth of sedation

Minimal	Anxiolysis, normal response to verbal stimulation.
Moderate	Conscious sedation, purposeful response to verbal or tactile stimulation
Deep	Purposeful response to repeated or painful stimuli*
General	Unarousable

* Reflex withdrawal from a painful stimulus is NOT considered a purposeful response

End time

Adults	Children
Orientated, conscious state same as before sedation	Can talk (conform age)
Can eat and drink, no nausea, pain well under control	Can sit (conform age)
Vital signs stable (breathing, circulation)	
Minimum of 2 hours after administration of a reversal agent	

PSA data collection form.

[interquartile range (IQR)], depending on normal distribution of the data. Categorical variables were presented as percentages using the modified Wald method (Agresti and Coull) to calculate 95% CI of proportions.

Results

A total of 351 paediatric patients received PSA in the study period. All paediatric patients who received PSA were included in the study. The patient characteristics are displayed in Table 1. The mean age was 9.5 years (minimum–maximum: 0–16; 95% CI: 9.1–10.0), and 57.9% were boys. The majority had an ASA class score I (95.4%), and 82.4% had a time to meal of less than 6 h. The most common indication for PSA was upper extremity fracture reduction (60.1%) (Table 2).

Esketamine was the most frequently used sedative (42.4%), followed by propofol (34.7%) and midazolam (22.9%). The intravenous route was the preferred route of administration (93.7%). In two cases, the type of sedative given was not recorded (0.6%). Esketamine was most frequently used for PSA in younger patients, whereas propofol was favoured in an older age group (Table 3). The median duration of PSA with sedatives through intravenous route was 20 min (n = 141, IQR: 14–33.5).

Table 1 Characteristics of paediatric patients undergoing procedural sedation and analgesia in the emergency department (n=351)

	n[a]	Mean (95% CI)
Age (years)	351	9.5 (9.1–10.0)
Body weight (kg)	333	38.2 (36.2–40.2)
Male (%)	349	57.9 (52.6–63.0)
ASA class (%)	350	
I		95.4 (92.7–97.2)
II		4.6 (2.8–7.3)
III+		0 (0–1.1)
Time to last meal (h)	261	
0–3		29.5 (24.3–35.3)
3–6		52.9 (46.8–58.8)
>6		17.6 (13.5–22.7)

ASA, American Society of Anesthesiologists; CI, confidence interval.
[a]Because of missing data, this is the total number of cases included in the analysis of the variable.

Adverse events

There were no serious adverse advents. We recorded adverse events in 11 (3.1%) patients (Table 4). The retrospective application of the World SIVA adverse event reporting tool showed that the majority of the adverse events were minimal or minor risk events. We had three patients with a moderate risk intervention/outcome: two patients with apnoea who required bag-valve-mask-assisted ventilation and one patient who needed a 3 h admission because of prolonged recovery after having received a subcutaneous dose of esketamine. This patient had no adverse sequelae. Finally, the retrospective hospital safety incident reporting databases' query of all participating centres did not yield any additional serious adverse events.

Amnesia, pain rating and procedure completion

Amnesia for the procedure was present in 86.8% of the 227 children in whom it was recorded. In the 31 patients who did not have amnesia, the median pain score was 2 (IQR: 1–4). The procedure was successfully completed in 93.9% (95% CI: 90.9–96.0; $n = 347$) of the cases.

Table 2 Indications for paediatric procedural sedation and analgesia in the emergency department ($n=351$)

Procedure	Cases [*n* (%)]
Dislocation – hip	1 (0.3)
Dislocation – shoulder	16 (4.6)
Dislocation – elbow	29 (8.3)
Dislocation – jaw	2 (0.6)
Dislocation – other	4 (1.1)
Fracture reduction – upper extremity	211 (60.1)
Fracture reduction – lower extremity	31 (8.8)
Abscess drainage	10 (2.8)
Foreign body removal	2 (0.6)
Wound care, face	15 (4.3)
Wound care, other	23 (6.6)
Other	5 (1.4)
Missing data	2 (0.6)
Total	351 (100.0)

Implementation success factors

We assessed the opinion of the author group ($n = 8$) with a retrospective survey on the implementation of paediatric PSA in the ED. According to this survey, the most important factor aiding the kick-start of PSA by EPs in the ED was inviting EP consultants from other countries experienced in PSA. Other factors that contributed were uniform national training and credentialing of EPs and residents, and availability of a PSA guideline and registration form. Coaching by anaesthesiologists and paediatricians played a lesser role.

Discussion

Until now, systematic evaluation of paediatric PSA safety and efficacy has been limited to experiences in countries where EM has been established for a long time. In our cohort of paediatric sedations performed by newly trained EPs, the adverse event rate (3.1%) was low when compared with international rates of 2.3–17.8% found in previously published papers [6–11]. More importantly, the events that occurred were all managed by the sedating EPs, and none of the children suffered any negative sequelae. Even though our study is underpowered to detect rare adverse events and our cohort consisted of mainly ASA class I paediatric patients older than 6 years of age, we believe our results add to the body of international evidence and suggest that PSA can be performed by EPs in paediatric patients, importantly even in a country where EM is in its starting phase.

The successful implementation of paediatric PSA, with high efficacy rates and lack of identified adverse events, can be explained by several factors. Having a foreign consultant EP experienced and confident in the procedure had two major advantages: this EP had immediate credibility in the eyes of the medical specialists and nursing staff, and it allowed residents and young attendings to provide hands-on care under supervision and with

Table 3 Sedatives used in patients undergoing procedural sedation and analgesia in the emergency department ($n=349$[a])

	Esketamine ($n=148$)		Propofol ($n=121$)		Midazolam ($n=80$)	
	n[b]	% (IQR or 95% CI)	*n*	% (IQR or 95% CI)	*n*	% (IQR or 95% CI)
Age [median (IQR)]	148	7 (6–11)	121	13 (10–16)	80	9 (5.5–12.5)
Total dose [median (IQR)] (mg/kg)	141[b]	0.5 (0.3–0.7)	118[b]	1.3 (0.8–1.8)	72	0.08 (0.03–0.12)
Sedation duration [median (IQR)] (min)	61[b]	30 (17.5–42.5)	61[b]	14 (9–19)	28	35 (16.5–53.5)
Sedation level: deep or higher[c]	101[b]	67.3 (57.7–75.7)	107	23.7–41.1	40	0 (0–8.8)
Opioid coanalgesia	148	2.8–10.3	121	60.7–76.9	80	51.3 (40.5–61.9)
Esketamine coanalgesia	148	0.0	121	2.8–11.5	80	1.3 (0.2–6.8)
Sedative use per age group (years)	148	–	121	–	80	–
0–5	36	59.0 (46.5–70.5)	4	2.6–15.7	21	23.8–47.0
6–11	83	43.9–59.1	45[b]	21.6–35.3	33	15.0–27.4
12–16	29	16.4–30.9	72	48.0–65.0	26	20.5 (14.4–28.3)
Adverse events	148	3.2–11.2	121	0.9–7.0	80	0 (0–4.6)
Amnesia	99	87.4–97.2	104	75.4–89.5	23	69.6 (49.1–84.4)
Success of procedure	146[b]	90.4–97.7	119	88.4–97.1	80	91.3 (83.0–95.7)

CI, confidence interval; IQR, interquartile range.
[a]In two cases, the sedative was missing, hence not included in this table ($n=351$).
[b]Because of missing data, this is the total number of cases included in the analysis of this variable.
[c]For esketamine: proportion of dissociated patients (instead of American Society of Anaesthesiologists level of sedation).

Table 4 Adverse events including their interventions and outcomes in paediatric patients undergoing procedural sedation in the emergency department (*n*=351)

Adverse events	Intervention	Outcome	*n* (%)	Sedative used[f] (*n*)
Recovery agitation[a]	Additional sedative[a]	No adverse outcome[a]	2 (0.6)	K=2
Emesis[a]	No intervention[a]	No adverse outcome[a]	4 (1.1)	K=4
Prolonged recovery[a]	No intervention[a]	Unplanned hospitalization[c,e]	1 (0.3)	K=1
Apnoea (>20 s)[d]	Bag valve mask-assisted ventilation[c]	No adverse outcome[a]	2 (0.6)	P=2
Allergic reaction (no anaphylaxis)[b]	Antihistamine[a]	No adverse outcome[a]	1 (0.3)	K=1
Bradycardia[b]	No intervention[a]	No adverse outcome[a]	1 (0.3)	K=1
Total sedation events	–	–	11 (3.1)	–

Score according to World SIVA adverse sedation reporting tool 2012: [a]minimal risk, [b]minor risk, [c]moderate risk.
[d]Not exactly comparable with SIVA standards, because of SIVA cutoff (>60 s)
[e]Prolonged recovery after intramuscular esketamine requiring observation with admission
[f]K=esketamine, P=propofol.

immediate feedback, in their own setting [13]. These EPs did not only function as supervisors for the PSA procedure but were mentors in a broader sense. They had met the same scepticism and resistance years before and were able to tackle certain criticisms and resistive manoeuvres upfront. Hence, when these first teaching hospitals commenced with adult PSA, it was with success [16], and paediatric PSA followed soon after. This system of mentorship created a snowball effect as trained EPs moved to other hopitals and introduced PSA in other EDs. The second step that aided progression of PSA to a national scale was when the NSEP acknowlegded PSA as one of the core competencies of the EP, and a special PSA section of NSEP was created. The tasks of this section were to create an evidence-based guideline and a PSA certification programme. The guideline and registration forms were made easliy accesible online on the NSEP website. The registration form (Fig. 1) could also be used as a checklist. This enforced a more uniform approach in presedation screening, medication choice/dosage, monitoring of sedation depth, scoring of vital parameters and discharge criteria. It set the standard for proper documentation. The PSA certification course was initially made mandatory for all certified EPs who provide PSA. The purpose was to ensure all Dutch EPs had the same level of knowledge on the national PSA guideline and were able to cope with adverse events. A few years later, PSA training was implemented into the national EM curriculum. The first credentialing programme consisted of a 2-day course and included topics like presedation screening and risk assessment, monitoring, pharmacology and paediatric PSA. Practical training comprised of the creation of multipe sedation plans, advanced airway management skill practice and adverse event scenario training. Guideline knowledge was tested with a written exam. Furthermore, the NSEP PSA section had regular meetings and discussions to evaluate this implementation process in a qualitative manner. The section provided updates on protocols and training with the emergence of new evidence and inputs from the EP community. Early data registration proved to be a vital tool to obtain information about the quality of PSA and was a confidence builder at the same time. We firmly believe that continuous data registration with regular publication and data sharing have kept the circle of quality and improvement going.

In short, we can concur with the findings of our colleagues in the UK and Ireland that a national approach to training standardizes practice and is key to developing a robust service across EDs, improving quality of care for children [12].

Last but not the least, PSA provided in the ED has the additional benefit of reducing healthcare costs [19]. We assessed the costs of a closed forearm reduction in a paediatric patient who receives PSA by an EP in the ED versus anaesthesia in the operating room (OR) in one of the participating hospitals. The cost ratio of PSA in the ED versus the OR was calculated to be approximately six times more expensive when performed in the OR.

Limitations

First, the number of sedations, when considering the time frame and amount of hospitals involved, are low. This can be explained by the fact that these were the very first paediatric sedations performed in The Netherlands by the first few trained EPs. The total number of EM paediatric patients eligible for PSA in the ED is not clear. Patients eligible for PSA were only registered when the EP was available in the ED. Second, 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; the number of complete data per variable is annotated in the tables. However, we included all patients with missing data, except when the patients' age was missing. 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. Third, in some patients sedated with sedatives without analgesic properties opioid comedication was not used (Table 3). Unfortunately, there was no specific field for some other types of analgesic premedication

on the data collection form. We believe this hiatus on the form may have led to under-reporting of analgesia and needs to be put in perspective. Fourth, because uniform reporting of adverse events was not proposed until 2012, we retrospectively applied the World SIVA reporting tool. Last, our cohort was too small and hence underpowered to provide insight into the occurrence of rare sentinel risk interventions and outcomes. Therefore, we cannot draw definitive conclusions on safety.

Conclusion

Paediatric PSA provided by the first EPs in The Netherlands showed appropriate levels of sedation and analgesia with a high rate of procedure completion and a low rate of adverse events. Our paper suggests that EPs can implement effective paediatric PSA even in a country where EM is at the first stages of development. Foreign mentorship, uniform training, guidelines and registration were the key ingredients for successful implementation of paediatric PSA. This service improves the quality of care for paediatric patients.

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Conflicts of interest

There are no conflicts of interest.

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