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A procedural sedation program minimising adverse events: a three-year experience from a tertiary paediatric emergency department.

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ABSTRACT

Introduction: A well-developed procedural sedation program in the paediatric emergency department can minimise adverse events. We examined how adherence to current best evidence, ensures safe delivery of paediatric sedation in a newly established tertiary paediatric hospital.

Methods: Our sedation service uses a robust provider training and privileging system, standardized policy and procedures, and rigorous data collection all within an evidence based clinical governance process. We examined sedation data from the first three years of operation.

Results: From July 2018 to May 2022, ketamine was used in 3388 of the 3405 sedations. The mean age of sedated children was 5.5 years (range 6 months to 17.8 years) and common indications were closed reduction of fractures and laceration repairs. A total of 148 (4.37%, 95% CI; 3.68%-5.06%) adverse events were documented, including 88 (2.59%, 95%CI; 2.06%-3.13%) cases of vomiting, 50 (1.48%, 95%CI; 1.07%-1.88%) cases related to airway and breathing with 40 (1.18%, 95%CI;

0.82% - 1.54%) cases of oxygen desaturation, 6 (0.18%, 95%CI;0.04%-0.32%) cases of laryngospasm, 4 (0.12% (95%CI; 0%-0.23%) cases of apnea.

Conclusion: This study presents a large single-centre data set on the use of intravenous ketamine in paediatric procedural sedation. Adhering to international standards and benchmarks for provider skills and training, drug administration and monitoring facilities, with a strict clinical governance process, patient safety can be optimised.

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- **What is already known on this topic** –

  Procedural sedation using Intravenous ketamine is used regularly in paediatric emergency departments for short procedures, but can be associated with serious adverse events. These adverse events are often related to unsafe practices and are preventable in many instances.

- **What this study adds**

  We present a case series of over 3400 procedural sedation interventions where adverse events were significantly lower than those quoted in the literature.

- **How this study might affect research, practice or policy**

  Adhering to international standards and benchmarks for provider skills and training, drug administration and monitoring facilities, with a strict clinical governance process, patient safety can be optimised.

INTRODUCTION

Injuries are among the most common reasons for paediatric emergency visits [1] and may often require procedural sedation. Provision of procedural sedation in the Emergency Department (ED) by non-anaesthetists can improve patient experience and enhance resource management, but serious untoward incidents can occur [2-5]. These adverse events are often related to unsafe practices and may be preventable [6]. The emerging body of sedation literature emphasises standards and benchmarks for provider skills/numbers and training, drug administration and monitoring facilities [7-13]. As one of the largest tertiary paediatric hospitals in the Middle East, Sidra Medicine has developed an integrated operational framework; procedural sedation outside the operating rooms is governed by the Procedural Sedation Committee, chaired by Anesthesia, vice chaired by Emergency Medicine. As a newly opened hospital, great efforts were made to ensure the development of a standardized process of oversight, education and training, care delivery and documentation of all procedural sedations. The committee was struck in 2016 with a view to ensure a long-term vision and plan with regards to safe sedation in the hospital, using expertise from both the Emergency Medicine and Anesthesia to develop the high standard required by the hospital. The committee is a multidisciplinary group, with stakeholders all having a voice in the development of policy and procedure. This arrangement we feel is somewhat unique, especially in the Middle East. Policy and Procedures developed have since been reviewed and confirmed in two separate Joint Commission International hospital accreditation processes, not only meeting standards for safe sedation across specialties and professions, but also meeting JCI accreditation standards. The committee governs

procedural sedation practice outside the operating theatres, when being provided by non anesthesiologists. The ED is the largest provider of sedations in the hospital, with much fewer numbers in PICU and NICU. Currently ward/outpatient clinic based sedations are provided by Anesthesia. We have examined how adherence to the current best evidence from the sedation literature [7] in the development of our sedation program has impacted our sedation safety profile in the first three years of our sedation service in the ED.

METHODS

Overview

The Sidra Medicine Paediatric Emergency Department opened in June 2018 and is part of a tertiary level 1 trauma center. The population of Qatar is 2.9 million, with children under 14 years constituting approximately 13%. Annual census is about 120,000 patients. The procedural sedation service was designed to standardize care and ensure patient safety, using quality assurance principles in design and implementation in addition to developing a curriculum for training that was standardized and evidence based. The training program uses adult education principles for a multidisciplinary audience that is scaffolded to ensure both knowledge and skill acquisition. However, as this was a new hospital with no 'before implementation' data to compare, we used published data on adverse events in procedural sedation for comparison and benchmarking [2-5].

The Intervention; a five-stage process

a) staff training and sedation privileging

A sedation training program was developed using Sidra Medicine procedural sedation policy and procedures process established by the Procedural Sedation Committee, which ensured all sedation providers met appropriate privileging requirements and practiced to the standards set by the Canadian Pediatric Society (CPS) [7], the American Academy of Pediatrics (AAP) [8], The Royal College of Emergency Medicine UK [9], American College of Emergency Medicine (ACEP) [10-12], and recommendations from the Society of Paediatric Sedation (SPS) [13].

Training involves pre reading of an evidence based procedural sedation manual, a full day interactive course on procedural sedation including case based sessions where knowledge is applied using real sedation cases. In addition, participants complete a simulated scenario to ensure competence in the pre assessment, medication delivery and monitoring during sedation, to demonstrate team-based communication skills, complete documentation and demonstrate adherence to policy/procedure [electronic supplement 1]. Successful completion of the course involves the successful completion of the scenario, and also completion of a written exam. Privileging requires successful completion of this course and a current paediatric advanced life support certification. Nursing staff also attend the one-day training program, and have a separate live sign off process with a sedation superuser. This training program was in place 6 months before the opening of the department and only physicians and nurses who have completed the program and are privileged through the Procedural Sedation Committee, can sedate children in the ED.

b) patient selection for procedural sedation

Children with ASA Class 1 and 2 are sedated in our emergency department. Typically, sedation is employed in our department for procedures with an anticipated duration of up to twenty minutes and includes children and infants over 3 months of age.

c) patient education and informed consent

Information on procedural sedation is provided with the help of an in-house educational video, available in English and Arabic, either displayed on a video display unit inside the patient cubicle or their mobile phones (accessed through a QR code). The sedation process is explained, and any concerns from the patient or family are addressed before the physician obtains a signed informed consent.

d) the sedation process

The sedation is carried out in a procedure room with full resuscitation capabilities. There is a dedicated sedating physician and nurse. Administration of sedatives is always preceded by completing a pre-sedation time-out checklist that ensures team and equipment readiness for sedation and the management of any adverse events. Ketamine is the most used agent for intravenous sedation in our department. This choice of sedative agent is based on the proven safety, efficacy, and worldwide popularity of ketamine for procedural sedation in children, and the use of a single agent reduces the risk of adverse events [2-4]. Ketamine provides a unique dissociative sedation characterised by profound analgesia and amnesia while preserving the respiratory drive, protective airway reflexes and hemodynamic stability [14]. During

sedation, patients are on continuous oxygen saturation, end-tidal CO_2 and ECG monitoring. Once the procedure is completed, patients are observed until they recover fully from sedation. The Modified Aldrete score [15], a post-anaesthetic recovery scoring system that includes the patient's activity, consciousness levels, and respiratory and hemodynamic status, is used to confirm discharge readiness. A score of 9 or above was required for discharge.

e) documentation, auditing, and risk management

An electronic template is used for sedation documentation that has mandatory fields to capture the sedation characteristics and quality performance indicators (Table 1). This information populates into an electronic database, which is extracted and audited monthly. Adverse events are reviewed and reported to the Procedural Sedation Committee and learning points are communicated to the ED team where required.

Data extraction and analysis

The study proposal for the retrospective analysis of three years of procedural sedation data was approved by Sidra Institutional Review Board (project reference 1913507-1) The anonymised data from 1st June 2018 to 31st May 2022 was extracted from the electronic medical records and analysed for the age of patients, indications of the sedation, sedative agent used, efficacy and adverse events.

RESULTS

The total number of intravenous sedations during the study period was 3405, with intravenous ketamine as a sole agent in 3388 (99.5%). The other intravenous agents

used included midazolam, fentanyl, and ketamine in combination with midazolam. There was one occasion where intravenous propofol was used by anesthesiology. Only the sedations that used intravenous ketamine exclusively were further analysed in this study. The mean age of the children undergoing intravenous sedation was 5.5 years (range; 6 months – 17.8 years) and are shown in Figure 1. The indications for sedation were; closed reduction of fractures (40.2%) and repair of lacerations (36.7%) forming the majority. Other common indications included repair of finger/toe tip injuries, abscess incision and drainage, burn debridement, foreign body removal, lumbar puncture, and diagnostic imaging. Three sedations (0.09%, 95%CI; 0%-0.1%) were unsuccessful despite receiving optimal dosing of ketamine, which included a laceration repair, incision drainage for a gluteal abscess and a closed fracture reduction, in all cases the patients were under five years of age. There was a total of 148 (4.37%, 95% CI; 3.68%-5.06%) adverse events in our cohort, which included 50 (1.48%, 95%CI; 1.07%-1.81%) that were related to airway and breathing, three instances of (0.09%, 95%CI; 0%-0.1%) hypotension that responded to fluid resuscitation, and 88 (2.59%, 95%CI; 2.06-3.13%) cases of vomiting. Among the airway and breathing complications, laryngospasm was noted in six (0.18%, 95%CI 0.04%-0.32%) children, hypoventilation or apnea requiring positive pressure ventilation in four children (0.12%, 95% 0%-0.23%) and desaturations that resolved with airway positioning with or without supplemental oxygen in 40 children (1.18%, 0.82%-1.54%). Six (0.18%, 95%CI 0.04-0.32) patients experienced severe emergence reactions during recovery that required pharmacological interventions. One patient developed self-limiting premature ventricular contractions after administering intravenous ketamine without hemodynamic compromise. There were no pulmonary

aspiration episodes or cardiopulmonary arrests in our cohort. Table 2 illustrates these adverse event rates compared to the four major case series publications of complication rates in the current literature [2-5]. The definitions used for the adverse event categories in these studies, with caveats about each study are in electronic supplement 2. The age group distribution of airway and breathing adverse events are given in Table 3.

The Procedural Sedation Committee meets quarterly and reviews the adverse events and processes, and feeds back to the ED in a collaborative process that ensures not just adherence of policy and procedure, but also adapts when adjustments need to be made at a committee level in terms of updating those policy and procedures. Two main issues were highlighted in the first three years; after reviewing sedations involving oral procedures and reflecting on the standards, we decided that oral procedures should not be completed in ED and instead would be performed in the operating theaters, and secondly, after a drug error, the concentration of ketamine being made available was simplified to one concentration instead of two.

DISCUSSION

We were establishing the service from initial opening of the department, thus we had no 'before intervention' data as our baseline for comparison. We have focused on adverse events as the key performance indicators for measuring the safety of our newly established service and used published adverse event rates from the evidence base of literature [2-6] for the primary measurement of the safety of our service. Published

clinical guidelines and policy statements were used to ensure a strong evidence base with standardized care [7-13].

Judging by the success and adverse event rate of our procedural sedation program using historical published data from other large studies as a comparison has potential problems; variation in the comparison populations, indications for the procedure, definitions and criteria used for their adverse events and variations in the way these were reported (e Supplement 1). The data from Green *at al* [2,3] were from 8282 subjects and was a systematic review of 32 papers, a mixture of retrospective and prospective data collection from different clinical environments, variable definitions used and variable outcomes reported. Grunwall *et al* [5] reported data from 22,645 children in a prospective collection of data within a consortium, however 64.5% of the children attended with semi elective radiologic interventions while fasting and only 12% (2738) data was from the emergency department. Sedation services were from academic, community, free-standing children's hospitals and pediatric wards within general hospitals with 60% of the sedation clinicians being from intensive care, and 3.5% anesthesia and 23% from ED. Bhatt et al [4] was a prospective, multicentre, observational cohort study from 6 pediatric emergency departments in Canada and performed by emergency physicians in acute situations. Even with these caveats, we feel the the comparisons with our data, is valid for assessing quality and safety. Clearly, these other centres also had a training and an accreditation process and we have used evidence from these studies and published standards to structure our service. Producing comparable and in some cases lower adverse event rates than published data reassures us that we have delivered a safe program.

Patient selection

The indications for procedural sedation were typical of a pediatric emergency department with a high volume of acute injuries. Complex laceration repair and closed reduction of fractures in acute situations constituted the vast majority (76.9%) of the procedures. More than 50% of the total number of sedations were in the age group between one and five years, reflecting the need for appropriate pain, anxiety and mobility control in treating injuries in this age group. Our group was more similar to the patient group in the Green [2-3] and Bhatt [4] papers but slightly different in comparison to patients in the Grunwall paper [5].

Overall success and completion of the procedure

Our success rate is significantly better than rates published in the literature with only 0.9% (95%CI, 0.0-0.01) of cases that required full anaesthesia in the operative theatre for completion [Bhatt [4] at 4.9% (95%CI, 4.5-5.6) and Grunwall [5] at 0.17% (95%CI, 0.12-0.23)]. We feel this is mainly due to clear criteria for both procedures qualifying for sedation and patient selection, and use of a single safe sedation agent. The other key to success was the detailed consenting and preparation of the families and child prior to the procedure and use of Child Play Specialists when available.

Airway and respiratory issues

The total number of airway and breathing-related adverse incidents reported were favourable in this series; the incidence of laryngospasm (0.18%; 95%CI, 0.04 - 0.32) was similar to Bhatt [4] (0.10%; 95%CI, 0.0-0.2) and Green [2] (0.30%; 95%CI, 0.18 - 0.42) but significantly lower than Grunwald [5] (0.40%; 95%CI, 0.32-0.48). The

incidence of desaturation and apnoea requiring airway manoeuvres and/or oxygen supplementation was quite low, although there was an increased incidence of airway and respiratory adverse events in children aged less than two years in our cohort (Table 3). This finding is in line with that reported by Green *et al* [2] but there was no peak in these events in children above thirteen years in our series.

Vomiting

Emesis was significantly less frequent in this cohort (2.59%; 95%CI, 2.06-3.13) compared to that reported by Green *et al* [3] (8.44%; 95%CI, 7.84-9.04) and Bhatt [4] (6.4%; 95%CI, 5.7-7.2). It is interesting that the incidence of vomiting in the Grunwall [5] paper was much lower than the other cohorts (1.1%; 95%CI, 0.9-1.2). Non fasting for emergency procedures has not demonstrated adverse events although it is unclear if there are patient sub-groups with an increased risk of vomiting that may benefit from pre-procedural fasting [10,16].

Other adverse events

Only severe episodes of recovery agitation that required pharmacological intervention were captured in our study, which amounted to six cases that were treated with intravenous midazolam (0.18%; 95%CI, 0.04 - 0.32) and again this is significantly less than reported in the Green [3] series (1.4%; 95%CI, 1.1-1.6). Reducing pre procedure anxiety and distress using distraction and other strategies in line with child life principles is advised [10], although support of such actions that can reduce post procedure agitation is limited [11]. Hypotension receiving fluid intervention occurred less frequently

in this series (0.09% 95%CI, 0.0-0.10) compared to that in Bhatt [4] series (0.1%;95%CI, 0.0-0.2). Grunwell *et al*, [5] reported three cardiac arrests and three cases of pulmonary aspiration with ketamine sedation. In this series, there were no cardiac arrests or pulmonary aspiration. No patients required hospital admission in our series as a result of any issue during procedural sedation.

A safe and efficient procedural sedation service is a key component in the delivery of child and family-centred care in paediatric emergency departments [17]. The importance of a sedation policy, standard operating procedures, and formal provider training in minimising sedation-associated complications is well-established in the sedation literature and in several policy statements and clinical practice guidelines [7-13]. The Society of Paediatric Sedation [13] has envisaged a set of core competencies for sedating physicians, including patient education, pre-sedation health and risk assessment, awareness of sedative pharmacology, airway management and identification and management of complications, including the ability to formulate rescue plans, effective team dynamics, and awareness of the local policies are crucial skills expected from a sedation provider. A robust organization-wide sedation regulatory framework, along with a privileging system that ensures core sedation competencies for providers, forms the bedrock of the procedural sedation service at Sidra Medicine.

The limitations in this project are that we delivered this intervention within our resources and facilities but these may not be generalisable to other units with different resources

in different countries. We have also used historical adverse events reports to define our success and this could be criticised; we have not had a 'before intervention' rate as this was an entirely new service. With well over a thousand sedations per annum from a single centre, our data is unique due to its size, exclusive intravenous route for ketamine administration, uniform criteria for patient selection, second physician responsible for the sedation, and our electronic health record-based documentation and adverse event reporting. The largest published reports [2-5] on ketamine sedation in children so far are derived from pooled data from multiple centres and are limited by heterogeneity involving patient selection, route of ketamine administration, initial and total doses, as well as co-administration of other agents.

CONCLUSION

This large, single-centre data set within a structured sedation program using trained providers, a rigorous clinical governance process, demonstrates a safe and effective service with an adverse event rate lower than the current published rates.

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COMPETING INTERESTS

There are no competing interests amongst the six authors

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CONTRIBUTION STATEMENT

GK, SD, SA, BB, CP KA were all involved with the inception of this paper. All authors were involved with the planning and conduction the data collection. KA, SD, BB, GA, SA developed and delivered the procedural sedation program. GK, SD, SA BB wrote the first draft of the paper and then re drafting and further analysis of data was by BB, CP and KA.

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Table 1: Mandatory sedation documentation parameters

1. **Procedure name**
2. **Medical and surgical history**
3. **Previous anaesthesia/sedation**
4. **ASA class**
5. **Airway assessment**
6. **Sedative agent used**
7. **Duration of sedation**
8. **Adverse events**
    - **Apnea, hypoventilation or desaturations**
    - **Hemodynamic instability**
    - **Cardiac dysrhythmia**
    - **Delayed recovery from sedation**
    - **Use of reversal agents**
    - **Adverse drug reaction**
    - **Unanticipated conversion to general anaesthesia**
    - **Hospitalisation for sedation related complication**
    - **Other significant changes from pre-procedural baseline**

Table 2:Incidence of adverse events [percentage with 95% confidence intervals] reported in this study and four other papers (referenced)

Adverse event*	Gok	n=3388	Bhatt (4)	All n=6296 Ketamine only n=3916	Green (2,3)	n= 8282	Grunwall (5)	n=22645
Laryngospasm	6	0.18 (0.04-0.32)	4	0.1 (0.0-0.2)	25	0.3 (0.18-0.42)	91	0.4 (0.32-0.48)
Desaturation	40	1.18 (0.82-1.54)	All=353 K =192	5.6 (5.0-6.2) 4.9 (4.2-5.6)	NR	NR	431	1.9 (1.7 - 2.0)
Apnoea	4	0.12 (0.0-0.23)	All =55	0.9 (0.3-1.4)	66	0.8 (0.61-1.00)	152	0.67 (0.57-0.76
Hypotension	3	0.09 (0.0-0.1)	All-7	0.1 (0.0-0.2)	NR	NR	NR	NR
Vomiting	88	2.59 (2.06-3.13)	K=253	6.4 (5.7-7.2)	699	8.44 (7.84-9.04)	241	1.1 (0.9-1.2)
Emergent phenomenon	6	0.18 (0.04-0.32)	NR	NR	115	1.4(1.1-1.6)	NR	NR
Not successful	3	0.9 (0.0-0.1)	All=314	4.9 (4.5-5.6)	NR	NR	39	0.17 (0.12-0.23)

* Definitions in e Supplement 1, K = ketamine, NR= not reported

Table 3: Airway and respiratory adverse events by age group

0-12 months (n= 62)	13-24 months (n= 430)	2- 13 years (n=2803)	>13 years (n=93)
1 (1.6%)	14 (3.2%)	34 (1.2%)	1 (1%)