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ORIGINAL RESEARCH

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Risk factors for sedation-related events during procedural sedation in the emergency department

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Abstract

Objective: To determine the nature, incidence and risk factors for sedation-related events during ED procedural sedation, with particular focus on the drugs administered.

Methods: Eleven Australian EDs enrolled consecutive adult and paediatric patients between January 2006 and December 2008. Patients were included if a sedative drug was administered for an ED procedure. Data collection was prospective and employed a specifically designed form. Multivariate logistic regression was employed to determine risk factors for sedation-related events.

Results: Two thousand, six hundred and twenty-three patients were enrolled (60.3% male, mean age 39.2 years). Reductions of fracture/dislocations of shoulders, wrists and ankles were most common. Four hundred and sixty-one (17.6%) cases experienced at least one airway event that required intervention. Airway obstruction, hypoventilation and desaturation occurred in 12.7%, 6.4% and 3.7% of all patients, respectively. Two thousand, one hundred and forty-six cases had complete datasets for further analyses. Increasing age and level of sedation, pre-medication with fentanyl, and sedation with propofol, midazolam or fentanyl were risk factors for an airway event ($P < 0.05$). Ketamine was a protective factor. Hypotension (systolic pressure <80 mmHg) occurred in 34 (1.6%) cases with midazolam being a significant risk factor ($P < 0.001$). Vomiting also occurred in 34 (1.6%) cases, 12 of whom required an intervention. One patient aspirated. Vomiting occurred after administration of all drugs but was not associated with fasting status. Other events were rare.

Conclusions: Sedation-related events, especially airway events, are common but very rarely have an adverse outcome. Elderly patients, deeply sedated with short-acting agents, are at particular risk. The results will help tailor sedation to individual patients.

Key words: *adverse event, emergency department, procedural sedation.*

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Introduction

Procedural sedation in the ED is commonly undertaken and a variety of sedative agents and techniques are employed. However, sedation-related events are commonly reported especially respiratory depression and obstruction, and to a lesser extent hypotension and vomiting.[1,2] Although there are numerous reports of the efficacy of a range of sedative agents, the large majority are underpowered to effectively examine and compare the incidence of related events. Furthermore, reports are often limited to specific drugs or populations (e.g. propofol, paediatrics) and have utilized heterogeneous methodology, often without account for important confounding variables.[3,4] Consequently, the comparative safety of these agents (as a reflection of unexpected events) is poorly understood.

The present study aimed to examine the nature and incidence of sedation-related events with the agents commonly used for ED sedation (midazolam, propofol, morphine, fentanyl, ketamine and nitrous oxide) and to determine which independent variables, among a comprehensive range, are significant risk factors for these events. The findings will identify sedative agents or patients at high risk of related events. This will inform the development of evidence-based, best-practice guidelines aiming to maximize efficacy and safety of procedural sedation in the ED.

Methods

The present study was undertaken as part of a multicentre, prospective, observational project, the complete details of which are reported elsewhere.[5] It was a prospective, analytical, observational project undertaken at 11 Australian EDs between January 2006 and December 2008. A consecutive sample of adult and paediatric patients who received parenteral sedation for a procedure in the ED was enrolled. Most data (weight, fasting status, details of defined sedation-related events, level of sedation, designation of the person in charge of the sedation and procedure outcome) were recorded prospectively, immediately after the procedure. Other data (demographics, nature of the procedure, time and dose of all drugs administered and disposition) were extracted, by the site investigator, after explicit review of the medical record.

The sedation-related events examined included respiratory events *that required an intervention*, vomiting, aspiration of stomach contents, hypotension (systolic BP <80 mmHg) or hypertension (systolic BP >180 mmHg), bradycardia (HR <60 /min) or tachycardia (HR >120 /min), and 'other' events. A respiratory event was defined as hypoventilation (<10 breaths/min) and/or oxygen desaturation (<90% mmHg) and/or an obstructed airway (partial/complete). Interventions for respiratory events included painful stimuli, chin lift or jaw thrust, insertion of an oro/nasopharyngeal airway, bag and mask ventilation, endotracheal intubation and the administration of flumazenil or naloxone.

The sample size calculation is reported elsewhere.[5] Only cases with complete datasets were included in the analyses. The dependent variables examined were the unexpected events, as defined above. The independent variables included sex, age, weight, nature of the procedure, deepest level of sedation, designation of the sedator, pre-medication and sedation drugs administered, and fasting status (time since last food/fluid ingested). Each independent variable was separated into either nominal or ordinal subgroups prior to analysis.

The Observer's Assessment of Alertness/Sedation Scale[6] was used to assess each patient's level of sedation. This 6-point ordinal scale comprised variables ranging from 'responded readily to name spoken in normal tone' (level 1) to 'did not respond to noxious painful stimulus' (level 6). It was easy to use and has proven validity and reliability.[6]

Univariate analyses were undertaken for the common sedation-related events (respiratory, vomiting, hypotension). The proportions of independent variables (or subgroups) among the cases that did/did not experience an event were compared using the χ^2-test. Multivariate logistic regression analysis was subsequently undertaken including all variables except sex, which had no association with any event. Stata 1999 statistical software 1999 (Stata, College Station, TX, USA) was used for data analysis. The level of significance was 0.05.

Results

A total of 2623 patients were enrolled. Of these, 1581 (60.3%, 95% CI 58.4–62.2) were male and the median (interquartile range, IQR) age was 34 (20–60) years. Reductions of fractured/dislocated shoulders, wrists and ankles were the most common procedures.[5] Airway events were most commonly seen. Overall, 461 (17.6%, 95% CI 16.2–19.1) patients experienced at least one

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airway event that required intervention. Airway obstruction, hypoventilation and desaturation occurred in 333 (12.7%, 95% CI 11.5–14.0), 166 (6.3%, 95% CI 5.4–7.4) and 97 (3.7%, 95% CI 3.0–4.5) cases, respectively. Chin lift, bag ventilation, painful stimuli and a pharyngeal airway were required in 403 (15.4%), 84 (3.2%), 66 (2.5%) and 45 (1.7%) cases, respectively. Naloxone and flumazenil were required in 9 (0.3%) and 6 (0.2%) cases, respectively.

Overall, 2146 cases had a complete dataset and were included in further analyses. Of these, 1306 (60.9%, 95% CI 58.8–62.9) were male and the median (IQR) age was 34 (19–60) years. The median (IQR) levels of sedation provided by the registrar and consultant were 4 (2–5) and 4 (2–6), respectively (Mann–Whitney *U*-test, $P < 0.001$). Sex, age and level of sedation were very similar for the cases not included ($P > 0.05$).

Within this group, respiratory events that required intervention were experienced by 447 (20.8%, 95% CI 19.1–22.6) cases (Table 1). On univariate analysis, a large number of variables were significantly associated with respiratory events. Multivariate analysis (Table 2) indicated that age ≥40 years, pre-medication with fentanyl, sedation with either propofol, midazolam or fentanyl, and a deep level of sedation were all risk factors for a respiratory event. Weight, procedure and fasting status were not associated with respiratory events. Having a trainee in charge and sedation with ketamine were protective factors. Notably, the administration of morphine for pre-medication or sedation was not associated with a respiratory event and ketamine has a protective effect. No patient who had morphine pre-medication or who received ketamine required intubation for a respiratory event.

Vomiting was experienced by 34 (1.6%, 95% CI 1.1–2.2) cases (Table 1). Univariate analysis revealed that young age, low weight, and sedation with nitrous oxide or ketamine were significant risk factors. Cases having a laceration repair also had a higher risk of vomiting. However, the large majority of these cases were children who had been administered ketamine. Pre-medication with morphine and sedation with propofol or fentanyl were protective factors. Although anti-emetic drug administration was not significantly associated with vomiting, none of the 83 cases who received an anti-emetic vomited. Although, fasting status was not significantly associated with vomiting, cases who had the shortest fasting period (<2 h) had a slightly increased risk. Multivariate analysis was not undertaken as the small number of cases who vomited precluded meaningful results.

A single (0.05%) case aspirated. This was an 83-year-old woman who was sedated for the relocation of a dislocated hip prosthesis. She had a past history of hiatus hernia repair and had fasted for 24 h before the procedure. She received pre-medication with morphine (2.5 mg) and was deeply sedated (level 6) with fentanyl (50 μg) and propofol (50 mg). Chin lift and bagging was provided for an obstructed airway and hypoventilation. Although no vomiting was observed, her oxygen saturation slowly dropped after the procedure. She required intubation and an intensive care admission for radiologically confirmed pulmonary aspiration.

Hypotension was experienced by 34 (1.6%, 95% CI 1.1–2.2) cases (Table 1), 27 (79.4%) of whom were administered a bolus of i.v. fluids. Univariate analysis revealed that age ≥40 years, sedation with midazolam and deep sedation were significant risk factors for hypotension. Patients who had an 'other' procedure also had a higher risk. Multivariate analysis was not undertaken as the small number of cases with hypotension precluded meaningful results.

Other sedation-related events among the original dataset of 2623 cases were uncommon. There were 42 (1.6%) cases of hypertension of whom only three (7.1%) required treatment (additional sedation). There were 75 cases of bradycardia of whom only two required treatment (i.v. fluids for both and aramine for one). There were 63 cases of tachycardia of whom only three required treatment (i.v. fluids for two and additional sedation for another). There were 29 other events reported. These included agitation (11 cases), seizure following morphine and propofol (2), twitching/jerking (1 after propofol/morphine, 1 after ketamine), drug allergy (3), laryngospasm (2), painful extravasation of propofol (2), nausea/retching (2), prolonged sedation (1) and excessive drooling (1). The nature of the event was not recorded in three cases.

Discussion

One important finding of the present study was that sedation-related events are common and are experienced by approximately one-fifth of cases. This highlights the need among those undertaking ED sedation for competency in event management.[7] Notably, with the exception of the case of aspiration, no case experienced an adverse outcome. It should not be concluded from this that procedural sedation is low risk, rather that patients are managed by emergency physicians

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Table 1. Univariate analyses of procedure-related events (n = 2146)

Variable	n	Cases of airway event		Cases of vomiting		Cases of hypotension	
		n (%)	P	n (%)	P	n (%)	P
Sex							
Male	1306	259 (19.8)	0.16	22 (1.7)	0.73	17 (1.3)	0.22
Female	840	188 (22.4)		12 (1.4)		17 (2.0)	
Age (years)							
<20	566	46 (8.1)	<0.001	28 (5.0)	<0.001	0 (0.0)	<0.001
20–29	407	76 (18.7)		2 (0.5)		4 (1.0)	
30–39	251	52 (20.7)		1 (0.4)		1 (0.4)	
40–49	172	39 (22.7)		1 (0.6)		5 (2.9)	
≥50	750	234 (31.2)		2 (0.3)		24 (3.2)	
Weight (kg)							
≤50	399	27 (6.8)	<0.001	28 (7.0)	<0.001	2 (0.5)	0.06
51–75	886	200 (22.6)		3 (0.3)		20 (2.3)	
76–100	744	189 (25.4)		3 (0.4)		12 (1.6)	
>100	117	31 (26.5)		0 (0.0)		0 (0.0)	
Procedure							
Dislocated shoulder	556	126 (22.7)	<0.001	1 (0.2)	<0.001	7 (1.3)	<0.01
Fractured wrist	280	51 (18.2)		1 (0.4)		0 (0.0)	
Fractured ankle	229	64 (28.0)		0 (0.0)		4 (1.8)	
Laceration repair	228	11 (4.8)		16 (7.0)		1 (0.4)	
All other	853	195 (22.9)		16 (1.2)		22 (2.6)	
Level of sedation							
1	274	6 (2.2)	<0.001	6 (2.2)	0.79	0 (0.0)	0.01
2	340	23 (6.8)		6 (1.8)		3 (0.9)	
3	237	43 (18.1)		3 (1.3)		2 (0.8)	
4	331	70 (21.2)		7 (2.1)		9 (2.7)	
5	454	133 (29.3)		5 (1.1)		6 (1.3)	
6	510	172 (33.7)		7 (1.4)		14 (2.8)	
Person in charge							
Consultant	1259	290 (23.0)	0.01	20 (1.6)	0.54	16 (1.3)	0.21
Registrar	852	153 (18.0)		12 (1.4)		17 (2.0)	
Resident	20	3 (15.0)		0 (0.0)		1 (5.0)	
Other	15	1 (6.7)		2 (13.3)		0 (0.0)	
Pre-medication drug given†							
Morphine	711	179 (25.2)	<0.001	4 (0.6)	<0.01	8 (1.1)	0.27
Fentanyl	304	84 (27.6)	<0.01	2 (0.7)	0.22	6 (2.0)	0.62
Anti-emetic	83	23 (27.7)	0.12	0 (0.0)	0.64	1 (1.2)	1.00
Sedation drug given†							
Propofol	1350	374 (27.7)	<0.001	4 (0.3)	<0.001	23 (1.7)	0.72
Midazolam	523	109 (20.8)	0.99	6 (1.2)	0.43	19 (3.6)	<0.001
Fentanyl	642	174 (27.1)	<0.001	4 (0.6)	0.02	14 (2.2)	0.19
Morphine	170	35 (20.6)	0.93	2 (1.2)	1.00	1 (0.6)	0.52
Nitrous oxide	184	8 (4.4)	<0.001	15 (8.2)	<0.001	0 (0.0)	0.11
Ketamine	354	30 (8.5)	<0.001	15 (4.2)	<0.001	3 (0.9)	0.35
Time last ate/drank (hours)							
00.00–01.59	224	41 (18.3)	0.11	6 (2.7)	0.62	6 (2.7)	0.28
02.00–03.59	563	108 (19.2)		7 (1.2)		7 (1.2)	
04.00–05.59	605	137 (22.6)		11 (1.8)		6 (1.0)	
06.00–07.59	334	74 (22.2)		6 (1.8)		5 (1.5)	
08.00–09.59	171	26 (15.2)		1 (0.6)		5 (2.9)	
≥10.00	249	61 (24.5)		3 (1.2)		5 (2.0)	
Totals	2146	447 (20.8)		34 (1.6)		34 (1.6)	

†*Compared with cases not given this drug (data not given).*

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Table 2. Variables significantly associated with sedation-related airway events on multivariate analyses ($n = 2146$)

Variable	OR	95% CI	*P*
Age (years)			
<20†	1.0	–	
20–29	1.4	0.9–2.2	0.19
30–39	1.5	0.9–2.4	0.14
40–49	1.8	1.0–3.0	0.04
≥50	2.3	1.5–3.5	<0.001
Level of sedation			
1†	1.0	–	
2	2.7	1.1–6.8	0.04
3	7.4	3.0–18.4	<0.001
4	9.9	4.0–24.0	<0.001
5	14.4	6.0–34.7	<0.001
6	20.4	8.5–49.2	<0.001
Person in charge			
Consultant†	1.0	–	
Registrar	0.8	0.6–1.0	0.04
Resident	0.6	0.1–2.3	0.44
Other	4.8	0.6–41.3	0.16
Pre-medication drug‡			
Morphine	1.3	1.0–1.7	0.05
Fentanyl	1.4	1.0–2.0	0.03
Anti-emetics	1.1	0.7–2.0	0.65
Sedation drug‡			
Propofol	1.8	1.2–2.6	<0.01
Midazolam	1.6	1.1–2.2	<0.01
Fentanyl	1.4	1.1–1.9	<0.01
Morphine	1.1	0.7–1.8	0.56
Nitrous oxide	0.9	0.4–2.1	0.81
Ketamine	0.6	0.3–1.0	0.04

†Reference group with which other groups are compared.
‡Compared with cases not given this drug.

and/or trainees adequately skilled in the appropriate management of unexpected events.

Respiratory events

Although most procedural sedation does not result in loss of protective airway reflexes,[8] our finding that respiratory events comprised the great majority of events is consistent with others.[2,9] Our definition of a respiratory event included the need for it to require an intervention. It is highly likely that other events occurred that did not require intervention and were, therefore, not documented, for example, transient partial obstruction. In this sense, our results might be an underestimation of all respiratory events. However, Bell *et al.*[9] reported that respiratory interventions are often not necessary given the transient nature of most events. Hence, the actual incidence of clinically significant respiratory events is difficult to determine.

The regression analysis revealed important, independent risk factors for respiratory events. It is not surprising that the elderly are at particular risk. They are more likely to have comorbidities and regular medication requirements, reduced physiological reserve and greater sensitivity to sedative agents. The drugs with significant respiratory event risk (fentanyl, propofol, midazolam) are potent agents and their respiratory depression effects have been reported previously.[2] However, the fact that these effects are relatively short-lived might contribute to their good safety profile. Notably, morphine was not a risk factor and, although its effect on respiratory depression is important in other settings[10] it is not in the ED sedation setting. The protective effect of ketamine is consistent with its effects of preserving airway reflexes.[11]

It is clear that an increased level of sedation is associated with an increased incidence of respiratory events. This is most evident as the sedation level 6 odds ratio was almost double that of level 4. This association was expected as profound suppression of the consciousness is often associated with depression of a range of respiratory, cardiovascular and other vital functions. In this regard, it is noteworthy that approximately one-quarter of cases were sedated to level 6, a level tantamount to general anaesthetic.

The apparent protective factor of having a registrar in charge of the sedation is of interest. This finding is likely related to the lower level of sedation provided by the registrars. Despite this lower level of sedation, it is notable that the registrars' procedural failure rate was similar to that of the consultants.[12] Alternatively, this apparent registrar 'protective factor' might have resulted from an 'alpha' error, a statistically significant finding by chance.

Vomiting

The drugs used routinely for procedural sedation are less emetic than the inhaled anaesthetic gases used for general anaesthesia.[13,14] Few cases (1.6%) in the present study vomited and this low incidence is consistent with the findings of others.[2,9,15–18] Procedural sedation is frequently undertaken in the ED regardless of the patient's fasting status.[15–17] It is likely that doctors do not delay a procedure when the patient is in considerable pain and that such pain might delay gastric emptying, in any case.[19]

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Importantly, fasting status was not associated with vomiting risk. Few ED studies have specifically examined vomiting during procedural sedation. Some report that fasting status has no impact upon the risk of vomiting[1,4,9,18,20] whereas others report that prolonged fasting might actually predispose to vomiting.[21] Interestingly, guidelines on procedural sedation[22] recommend determining patient fasting status but make no recommendation for the application of this information. Although fasting status might have limited importance, it is worthy of consideration in the pre-sedation risk evaluation of individual patients and decisions made accordingly.[3,4,8,23] For example, for a non-fasted patient who requires sedation without delay, drugs associated with nausea and vomiting might best be avoided.

The variables that were found, on univariate analyses, to be risks for vomiting were expected. Children have a propensity to vomit[1] and nitrous oxide[24] and ketamine[17] are known to be more emetic than other drugs. However, as regression analyses could not be undertaken, we cannot conclude that these are independent factors. Indeed, it is very likely that there were clear interactions between these variables. For example, children have low weight and are more frequently administered nitrous oxide and ketamine for suturing and less common procedures. Interestingly, morphine was found to be a protective factor. Morphine can induce nausea and vomiting although the routine use of an anti-emetic with morphine is considered unnecessary in the trauma setting.[25] Our findings are consistent with these recommendations. Propofol was also a protective factor and its anti-emetic properties have been reported previously.[26]

The low incidence of vomiting in the present study, and the finding that no patient who vomited actually aspirated, is consistent with the reports of others that the absolute risk of aspiration is very small.[1,4] Only one case of aspiration has been reported previously.[27] It is likely that a variety of patient-specific factors determine the depth of sedation at which they become unable to protect themselves from significant aspiration.[28] Our case of aspiration is instructive, especially as she did not vomit and was not administered drugs at risk of causing vomiting. Silent aspiration has been observed during normal sleep.[29,30] Although conjecture, it is possible that her old age and the manual ventilation she received, in the setting of previous hiatus hernia surgery, partially inflated her stomach and left her prone to silent aspiration during her deep sedation.[31] There was no suggestion that she was clinically ill prior to the procedure and earlier aspiration or other respiratory disease was highly unlikely.

Hypotension

Hypotension was also an uncommon event and this is consistent with other reports.[2] Most patients were treated with a fluid bolus and no adverse outcomes were observed. The level of hypotension in our definition (<80 mmHg systolic) was low and, although the data were not collected, it is very likely that considerable numbers of cases had BP falls to between 80 and 100 mmHg. Also, our observed incidence of hypotension is likely to be an underestimate as BP was not measured continuously. The elderly are particularly at risk because of their physiological characteristics described above. Midazolam is known to have hypotensive properties, especially if substantial doses are administered rapidly.[32] The finding that the level of sedation was a risk factor was expected as deep sedation is known to have significant adverse effects on cardiovascular reflexes. Like vomiting, these univariate data cannot identify truly independent risk factors.

Patient assessment

Patient risk assessment is important prior to procedural sedation and should include a consideration of duration of the procedure, expected sedation depth required, drug selection tailored to the patient and fasting status.[8] The findings of the present study might inform the appropriate selection of a sedation regimen for an individual patient. For example, an 85-year-old patient with cardiovascular disease and hypertension is at risk of respiratory events and hypotension. In order to minimize these risks, fentanyl, midazolam and deep sedation should be avoided. Judicious doses of morphine and propofol would offer a reasonable alternative.

Limitations

A number of the present study's limitations have been reported elsewhere.[5] In this part, there were few cases of vomiting and hypotension. Consequently, multivariate analyses were inappropriate and truly independent risk factors could not be determined. A truly consecutive sample was not achieved. The number of missed cases could not be determined retrospectively as sedation cases are not specifically classified. However, the number of missed cases is likely to have been small.[5] Some cases were excluded from analysis because of missing data. It is possible that missing cases and data contributed to selection bias. Significant measurement bias is unlikely as most data were specific and collected

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prospectively on purpose-designed documentation. However, we relied upon self-reporting of sedation-related events. This might have been affected by prevarication bias and underreporting. Data collected on explicit chart review were also specific and not open to interpretation. Some subjectivity was inherent in determination of the level of sedation. However, the Observer's Assessment of Alertness/Sedation Scale tool has clearly defined sedation levels and has been validated previously. External validity is likely to be good as the large sample size was enrolled at a number of EDs across Australia.

Directions for future research

We recommend that large collaborative studies or a national sedation registry be considered. Data from these initiatives would be valuable in informing the development of detailed risk profiles for individual drugs, demographics and other patient variables. These profiles will allow the tailoring of sedation techniques to individual patients in order to minimize the risk of sedation-related events. Databanks would also provide sample sizes large enough for detailed analysis of less common events, inform quality assurance audits and allow further research into specific research questions.

Conclusion

Sedation-related events in the ED are common although adverse outcomes are very rare. Respiratory events are particularly common and are experienced by approximately one-fifth of cases. Increasing age and level of sedation, pre-medication with fentanyl, and sedation with propofol, midazolam or fentanyl are significant risk factors for an airway event. Very deep sedation should be avoided if possible. Vomiting and hypotension are uncommon events and independent risk factors are yet to be determined. Other events, including aspiration, are rare. A knowledge of the risks associated with sedative drugs, demographics and other patient variables will assist in the selection of appropriate sedation techniques for the individual patient.

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Competing interests

DMcDT and AH are Section Editors, Original Research for *Emergency Medicine Australasia*.

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