CHAPTER
11

Risk factors: patient and organisational


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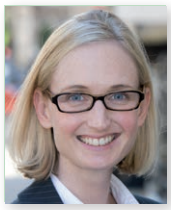
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HEADLINE

11.1. This chapter presents a numerical analysis of 110 Certain/probable AAGA (Class A) reports to NAP5. This cohort, which provides the best quality data for analysis was compared with data from the NAP5 UK anaesthetic Activity Survey. This cohort is considerably larger than many previous analyses attempting to identify risk factors. Factors increasing risk of AAGA appear to be: female gender; age (younger adults, but not children); obesity; seniority of anaesthetist (junior trainees); previous AAGA; out of hours operating; emergencies; type of surgery (obstetric, cardiac, thoracic, neurosurgery), and use of neuromuscular blockade. The data is also supportive of the following as risk factors: difficult airway; obesity with difficult airway. The following factors were not risk factors for AAGA: ASA; race; use or omission of nitrous oxide.

BACKGROUND

11.2 A wide variety of patient (and organisational) factors have been identified as being associated with an increased incidence of AAGA (Table 11.1), but the results are markedly inconsistent. In Table 11.1, factors in blue in the first column are associated with directly conflicting results in the literature as to whether they increase, have no effect or even decrease risk of AAGA.

11.3 In addition to risk factors in Table 11.1, reduced drug doses or interruption of drug administration are cited by most sources as causes of AAGA. In historical series, anaesthetic techniques associated with no volatile agent are, unsurprisingly, associated with an increase in AAGA (Errando et al., 2008). However, as this is of historical interest only, it is not considered further here.

11.4 In this chapter we consider patient and organisational factors associated with AAGA. The chapter is largely a numerical analysis. We have used the Class A (Certain/probable) cases reported to NAP5, and have compared the incidence of potential risk factors to that reported in patients undergoing general anaesthesia in the Activity Survey.

Gender

11.5 Most studies report an increased incidence of AAGA in women. The evidence supporting this is conflicting (see Table 11.1). As Caesarean delivery with general anaesthesia has traditionally been accepted as having an increased risk of awareness, any study that includes obstetrics will be likely to demonstrate an increased incidence in women. Women appear to recover more quickly from general anaesthesia than men (Buchanan et al., 2006; Gan et al., 1999) which may put them at increased risk of AAGA at emergence and might indicate reduced sensitivity to anaesthetic agents.

Table 11.1. Risk factors associated with AAGA in large adult cohorts (yes = risk factor; no = not risk factor). Factors in column 1 shown in blue have conflicting results between studies regarding their role as a risk factor for AAGA. (BZ = benzodiazepines; NMB = neuromuscular blockade)

	Ranta et al., 1998	Domino et al., 1999	Sandin et al., 2000	Sebel et al., 2004	Wennervirta et al., 2002	Errando et al., 2008	Ghoneim et al., 2009	Aranake et al., 2013
Number of cases in cohort	2,612	-*	11,785	19,575	3,843	3,991	-*	
Certain/probable case of AAGA	10	61	14	25	4	39	271	
Possible cases of AAGA	9	0	4	46	7	5	0	
Female gender	No	Yes	Yes	Yes			?	Yes
Age	No	Younger		??			Younger	Younger
ASA class	No	Low		High				Low
Obesity	No						No	Yes
Difficult airway		?					No	
Previous AAGA			?				Yes	Yes
BZs protective			No			Yes	Yes	
Urgency of surgery		Elective			No	No		
NMB		Yes	Yes			No	No	
Concomitant drugs					No			Yes**
Alcohol								Protective
Human factors		Yes	Yes			Yes		
TIVA						Yes	Yes	
Type of surgery	No	Obstetric, Gynaecology		Abdominal, Cardiac, Thoracic, Eye.		Obstetric	Obstetric, Cardiac	
Time of day						Night		

* case series of reports exclusively of AAGA; ** opiate and anticonvulsant users.

11.6 Medicolegal series of cases of awareness in the UK and the USA have demonstrated that a higher number of claims come from women. Domino et al. (1999) reported that 77% of US claims were from women. Mihai et al. (2009) reported that 74% of UK claims were from women and that 29% of claims arose in obstetric general anaesthesia. This may indicate that gender influences reporting rates as well as susceptibility to AAGA.

Age

11.7 Age affects anaesthetic sensitivity and MAC (Nickalls & Mapleson, 2003). There are conflicting reports on the effect of age on the risk of AAGA (see Table 11.1). Paediatric patients have been considered at increased risk of AAGA, and this is discussed in more detail in Chapter 15 (Paediatrics).

ASA score

11.8 Some studies have reported that patients with a higher ASA score, are at increased risk of AAGA and others have reported the converse (see Table 11.1). Intentionally reduced doses of anaesthetic drugs, both at induction and during the maintenance phase, because of concerns over cardiovascular and other effects, may contribute to this. Bogetz & Katz (1984) reported this when identifying a high incidence of AAGA in patients after surgery for major trauma with minimal anaesthesia. In modern practice, improved monitoring, early use of vasopressors and the facility to manage patients for extended periods in recovery and critical care areas might be expected to reduce this incidence. This is discussed further in Chapter 8 (Induction) and Chapter 17 (ICU).

11.9 In conflict with this, Domino et al. (1999) reported that claims associated with AAGA were more common in patients with a low ASA (possibly because they are more robust, they need higher concentrations of anaesthetic).

Obesity

11.10 Obesity has been identified as a risk factor for AAGA (see Table 11.1). There are many potential reasons – (see Chapter 6 (Main Results) and Chapter 8 (Induction) for further discussion. Inadequate drug dosing is one potential cause. Obesity significantly affects the pharmacokinetics and pharmacodynamics of many anaesthetic agents. Obesity is associated with increased body fat content, increased lean body mass, increased blood volume and cardiac output, reduced total body water and alterations in plasma protein binding: overall volume of distribution is increased (Ingrande & Lemmens, 2010). Peak drug plasma concentrations may be reduced by increased total blood volume and changes in regional blood flow. Oxidative and reductive hepatic metabolism is increased, and increased renal blood flow and glomerular filtration rate leads to increased renal clearance of many anaesthetic drugs (Marik & Varon, 1998). Due to the cardiovascular and respiratory effects of obesity, pharmacodynamic effects of anaesthetic drugs may be altered leading to an increase in risk of complications (e.g. hypoxia with opioids; Adams & Murphy, 2000). Current recommendations (Nightingale et al., 2013) stipulate a reduction in dose (on a weight basis) of induction agents, muscle relaxants (except suxamethonium), opioids and TCI propofol.

Difficult airway management

11.11 Patients in whom airway management is difficult may be vulnerable to AAGA due to offset of the effect of induction agents, failure to administer anaesthesia during difficult airway management or failure of volatile agents to reach the patient when mask ventilation is ineffective or there is airway obstruction (see Chapter 8, Induction, for further discussion).

11.12 Obesity is a risk factor for difficult airway management (Langeron et al., 2014) including difficult mask ventilation (Langeron et al., 2000), difficult supraglottic airway insertion (Ramachandran et al., 2012), failed mask ventilation with failed intubation (Kheterpal et al., 2013) and major complications of airway management (Cook et al., 2011). This may further increase the risk of AAGA in the obese population.

Resistance to anaesthesia and genetics

11.13 AAGA may arise from an intrinsic resistance to anaesthesia. Ghoneim et al. (2009) reviewed 271 published reports of AAGA, and reported that 1.6% described a previous history of awareness. In the BAG-RECALL study, 11% of patients with definite or possible AAGA had a previous history of AAGA (Avidan et al., 2011). In most epidemiological studies of AAGA, cases are reported with no apparent cause (e.g. Sandin et al., 2000, Errando et al., 2008).

11.14 Most recently Aranake et al. (2013) reported a secondary analysis of 26,490 patients enrolled in three major trials investigating AAGA (B-Unaware, BAG-RECALL and MACS), including 241 patients

with a previous history of AAGA. Patients with a history of AAGA had a 5-fold greater incidence of AAGA (1.7%) during the trials than a group of paired controls who did not (0.3%): anaesthetic management did not differ between the groups. In an accompanying editorial Pryor & Hemmings (2013) raised the possibility that increased risk of awareness with recall might be due as much to variations in memory formation and retention as to issues relating to anaesthetic sensitivity. See also Chapter 9 (Maintenance).

11.15 In Aranake et al.'s study the relationship between volatile anaesthetic concentration and BIS differed between the two groups. Patients with a history of AAGA had a lower BIS score (~5 units) at low anaesthetic concentrations and BIS changed less for given changes in anaesthetic concentration compared to controls.

11.16 The reasons why some patients may be insensitive to anaesthetic drugs and require higher doses are not completely understood but pharmacogenetics are likely to be important. Ezri et al. (2007) investigated MAC requirements in three ethnic groups and demonstrated variation with ethnicity. A limitation of this study was that confounding characteristics such as lifestyle were not accounted for.

Concomitant drug and alcohol use

11.17 While it is held that concomitant use of drugs (opioids, benzodiazepines, anticonvulsants and alcohol) may alter the risk of AAGA, there is very little robust evidence to support this and what there is, is conflicting (see Table 11.1). In particular, early papers considered at length whether (omission of) benzodiazepine premedication pre-disposed to AAGA – with conflicting results. Sedative drugs might alter anaesthetic requirements by pharmacokinetic effects (such as altered metabolism e.g. inducing hepatic cytochrome P450) leading to altered drug metabolism. Drug and alcohol use may also alter pharmacodynamic sensitivity to anaesthetic agents leading to resistance.

Other factors

11.18 Organisational factors such as urgency of surgery, day and time of anaesthesia, seniority of the anaesthetist, whether the anaesthetist is a locum and other factors are of interest in determining risk for AAGA. These are also considered here.

NAP5 CASE REVIEW AND NUMERICAL ANALYSIS

11.19 There were a total of 110 class A (Certain/probable) reports of AAGA. These reports were the most complete and contained the most reliable information on patient and organisational factors. Our analysis is therefore restricted to these 110 patients. Statistical comparisons were made using the chi-squared test (*Analyse It*, Leeds University, UK).

11.20 Throughout, we use the data from 15,460 patients undergoing general anaesthesia in the Activity Survey as a comparator, to examine whether certain characteristics were more commonly present in patients reporting AAGA than in the UK surgical population. Where data was not available ('not recorded') this was not analysed but is included for AAGA reports for clarity. While any association identified strictly implies increased risk of *reporting* AAGA, for most factors it is reasonable to assume this is due to an increased risk for AAGA itself. TIVA is not considered here as it has a whole chapter dedicated to it (Chapter 18 TIVA).

Gender

11.21 Females were significantly over-represented in Class A reports compared with the Activity Survey ($p<0.026$; Table 11.2). If the 13 obstetric reports are excluded the proportion of female cases falls to 58% but still remains significantly higher than males ($p<0.05$).

Table 11.2. Patient gender in Class A reports and Activity Survey general anaesthetics ($p = 0.026$ for male vs female)

	Class A cases (%)	Activity Survey (%)
Female	70 (63.6)	8,109 (53.0)
Male	40 (36.4)	7,183 (47.0)
Total	110	15,292

Race

11.22 Table 11.3 indicates that the distribution of patients of different racial origin rates was the same in Class A reports of AAGA and in the Activity Survey.

Table 11.3. Ethnic origin in Class A reports and Activity Survey general anaesthetics (p = 0.42 for difference in distribution of race AAGA reports vs Activity Survey)

	Class A cases (%)	Activity Survey (%)
Asian/Asian-British/ Indian	4 (4.1)	837 (5.5)
Black/Afro-Caribbean	1 (1.0)	430 (2.8)
Chinese/Japanese/ SE Asian	0 (0.0)	86 (0.6)
White Caucasian	92 (94.8)	13,694 (89.5)
Mixed/Other	0 (0.0)	256 (1.7)
Total	97	15,303
Not recorded	13	157

Age

11.23 The distribution of ages in Class A reports to NAP5 differed significantly from that in the Activity Survey, p<0.0001 (Table 11.4). The distributions suggest increased risk of reports of AAGA in younger and middle aged adults, but not in children. This is discussed further in Chapter 15 (Paediatrics).

Table 11.4. Age distribution (years) in Class A reports and Activity Survey general anaesthetics (P<0.0001 for difference in age distribution AAGA reports vs Activity Survey)

	Class A cases (%)	Activity Survey (%)
<1	0 (0.0)	197 (1.3)
1-5	1 (0.9)	1,004 (6.6)
6-15	4 (3.7)	1,447 (9.5)
16-25	15 (13.8)	1,424 (9.3)
26-35	26 (23.9)	1,701 (11.1)
36-45	19 (17.4)	1,926 (12.6)
46-55	20 (18.2)	2,128 (13.9)
56-65	12 (11.0)	2,128 (13.9)
66-75	8 (7.3)	1,928 (12.6)
76-85	3 (2.8)	1,162 (7.6)
≥86	1 (0.9)	267 (1.7)
Total	109	15,312
Not recorded	1	148

ASA physical status

11.24 Table 11.5 indicates that the distribution of patients' ASA grades was the same in Class A reports of AAGA and in the Activity Survey.

Table 11.5. ASA physical status in Class A reports and Activity Survey general anaesthetics (p = 0.23 for comparison of distribution AAGA vs Activity Survey)

ASA Grade	Class A cases (%)	Activity Survey (%)
1	34 (31.2)	6,274 (41.2)
2	54 (49.5)	6,041 (39.6)
3	18 (16.5)	2,491 (16.3)
4	3 (2.8)	395 (2.6)
5	0 (0.0)	44 (0.3)
Total	109	15,245
Not recorded	1	215

Obesity

11.25 There was a disproportionately high proportion of obese patients in Class A reports of AAGA compared with the Activity Survey general anaesthetics (see Table 11.6) (p=0.01).

Table 11.6. Patient body habitus in Class A reports and Activity Survey general anaesthetics (p=0.01 for comparison of distribution AAGA vs Activity Survey)

	Class A cases (%)	Activity Survey (%)
Underweight	4 (4.0)	463 (3.1)
Normal	36 (36.4)	8,004 (54.3)
Overweight	27 (27.3)	3,514 (23.8)
Obese or morbidly obese	32 (32.3)	2,753 (18.7)
Total	99	14,734
Not recorded	11	726

Difficult airway management

11.26 In the AAGA Class A cohort, 92 airways (84%) were managed with a tracheal tube (2 double lumen), 13 with a supraglottic airway device, three with facemask, one with a Hudson mask and one with direct 'tracheal ventilation'. In the Activity Survey a tracheal tube was used in 44.6% of cases and a supraglottic airway (SAD) in 51.3%. Difficulty with airway management was a factor in 27 Class A cases (26.5% of those for which data was available (Table 11.7). Twenty three reports described difficult intubation, five reported difficult mask

ventilation, three reported difficult SAD insertion and one reported bronchospasm; in five cases there were combined difficulties. Six inductions were combined gaseous and intravenous (and 104 intravenous) but none of these gaseous inductions involved difficult airway management. Eight (38%) of the cases of primary difficult intubation and Class A AAGA occurred during rapid sequence induction, which was used in <8% of general anaesthetics in the Activity Survey. This topic is discussed in more detail in Chapter 6 (Main Results) and Chapter 8 (Induction).

Table 11.7. Difficult airway management in Class A reports and in Activity Survey general anaesthetics

	Class A cases (%)
No	75 (73.5)
Yes*	27 (26.5)
Not recorded	8
Total	110

*21 difficult intubation; 3 difficult mask ventilation and difficult insertion of supraglottic airway device; 2 difficult mask ventilation followed by difficult or failed intubation, 1 bronchospasm during intubation.

Obesity and difficult airway management

11.27 Of the 32 obese or morbidly obese Class A patients, ten were difficult to intubate, 21 were not, and in one case this was not recorded. Of reports of AAGA in obese patients, 31% involved difficult airway management and 37% of the cases of difficult airway management associated with AAGA were in obese patients.

Anxiety

11.28 Six (6.1%) of 99 Class A patients were identified as anxious. A total of four sedative premedications were administered (three benzodiazepine and one opioid/atropine) to three anxious and one non-anxious patient.

Anaesthetic resistance and history of AAGA

11.29 In 13 (22%) of 104 Class A reports in which preventability could be assessed, it was deemed that AAGA was unpreventable and anaesthetic conduct was good (i.e. no clear cause for AAGA). In ten (77%) of these cases the Panel considered one possibility was intrinsic anaesthetic insensitivity.

11.30 Forty eight Class A reports provided information about previous general anaesthetics and two (4.2%) patients reported previous AAGA. Twenty-eight class A patients underwent a subsequent anaesthetic, and in 24 cases where information was available, there was no report of subsequent AAGA (Table 11.8). These data support the suggestion that a past history of AAGA should be considered a risk factor for AAGA.

Table 11.8. Occurrence of AAGA during prior and subsequent general anaesthetics in Class A reports

	Class A cases (%)
Previous general anaesthetic	67
No AAGA	46 (95.8)
AAGA	2 (4.2)
Not recorded	19
Subsequent general anaesthetic	28
No AAGA	24 (100.0)
AAGA	0 (0.0)
Not recorded	4

Drugs

11.31 The frequency of drugs use that might influence risk for AAGA, in Class A reports is shown in Table 11.9. In many cases, patients were taking multiple relevant agents. Comparative data from the Activity Survey is not available.

Table 11.9. Relevant drug use in Class A reports

	Class A cases (%)
Opioids (including tramadol)	19 (17.3)
Antidepressants	10 (9.1)
Anticonvulsants*	8 (7.3)
Benzodiazepines	4 (3.6)
Excessive alcohol	6 (6.5)
Illicit drugs	1 (0.9)
Beta blockers	11 (10.0)
Thyroxine	5 (4.5)
Steroids	5 (4.5)
Beta2 agonists	20 (18.2)
None of the above	60 (54.5)
Total	110

* all gabapentin or pregabalin

Time of day

11.32 There was a disproportionately high proportion of evening and nightime operating in Class A reports of AAGA compared with the Activity Survey general anaesthetics (see Table 11.10), $p<0.0001$.

Table 11.10. Time of day anaesthesia started in Class A cases and Activity Survey general anaesthetics. Day (08:00 –17:59), Evening (18:00–23.59), Night (00.00–07:59). (p<0.0001 for comparison of distribution AAGA vs Activity Survey)

	Class A cases (%)	Activity Survey (%)
Day	87 (87.0)	14,311 (93.7)
Evening	17 (17.0)	723 (4.7)
Night	6 (6.0)	240 (1.6)
Total	110	15,274
Not recorded	0	186

Day of Week

11.33 The distribution of weekday and weekend operating in Class A reports is shown in Table 11.11. Comparative data from the Activity Survey is not available.

Table 11.11. Day anaesthesia started in Class A cases

	Class A cases (%)
Weekday	90 (83.3)
Weekend	18 (16.7)
Not recorded	2
Total	110

Urgency of surgery

11.34 There was a disproportionately high proportion of urgent and emergency anaesthesia cases in Class A reports of AAGA compared to the Activity Survey general anaesthetics (see Table 11.12), p<0.0001.

Table 11.12. Urgency of surgery in Class A cases and Activity Survey general anaesthetics (P<0.0001 for the comparison of distribution AAGA vs Activity Survey)

	Class A cases (%)	Activity Survey (%)
Elective	59 (53.6)	10,416 (71.3)
Expedited	6 (5.5)	957 (6.6)
Urgent	32 (29.1)	2,892 (19.8)
Immediate	13 (11.8)	337 (2.3)
Total	110	14,602
Not recorded	0	858

Seniority of staff

11.35 There was a disproportionately high proportion of junior anaesthetists in Class A reports of AAGA compared with the Activity Survey general anaesthetics (see Table 11.13) (p = 0.003). Career grade staff were also over-represented numerically but to a lesser extent.

Table 11.13. Seniority of staff in Class A cases and Activity Survey general anaesthetics (p = 0.003 for the comparison of distributions AAGA vs Activity Survey)

	Class A cases (%)	Activity Survey (%)
Consultant	65 (64.4)	11,547 (75.0)
Career grade	20 (19.8)	2,197 (14.3)
SpR 4-7	8 (7.9)	1,080 (7.0)
SpR3 / CT3	3 (3.0)	200 (1.3)
CT1-2	5 (5.0)	176 (1.1)
Total	101	15,200
Not recorded	9	260

Locums

11.36 Table 11.14 indicates that the presence of a locum anaesthetist was associated with an increase in the prevalence of Class A reports of AAGA, but this did not reach statistical significance.

Table 11.14. Substantive and locum staff in Class A cases and Activity Survey general anaesthetics (P = 0.077 for comparison of distributions AAGA vs Activity Survey)

	Class A cases (%)	Activity Survey (%)
Substantive	88 (88.0)	14,040 (92.6)
Locum	12 (12.0)	1,115 (7.4)
Total	100	15,155
Not recorded	10	305

Type of surgery

11.37 The distribution of types of surgery in Class A reports of AAGA differed significantly from that in Activity Survey general anaesthetics (see Table 11.15), p<0.0001. Surgical specialties over-represented by more than two-fold in the reports of AAGA were:

- Obstetrics; 14.8-fold
- Thoracic; 4.1-fold
- Cardiac; 3.3-fold
- Neurosurgery; 2.5-fold

11.38 Of note: there is uncertainty over the accuracy of the obstetric data reported in the Activity Survey (See Chapter 16 (Obstetric) for further discussion) however even a 2-fold error in data would still leave a 7-fold excess of obstetric cases in Class A AAGA reports.

Table 11.15. Surgical specialty in Class A cases and Activity Survey general anaesthetics (p = 0.001 for comparison of distributions AAGA vs Activity Survey)

	Class A cases (%)	Activity Survey (%)
Orthopaedics and trauma	12 (11.0)	3,389 (22.1)
General	31 (28.4)	3,183 (20.8)
Gynaecology	11 (10.1)	1,789 (11.7)
ENT	16 (14.7)	1,478 (9.6)
Urology	1 (0.9)	1,384 (9.0)
Dental	0 (0.0)	611 (4.0)
Plastics	2 (1.8)	556 (3.6)
Maxillofacial	0 (0.0)	411 (2.7)
Ophthalmology	3 (2.8)	271 (1.8)
Neurosurgery	6 (5.5)	325 (2.1)
Gastroenterology	1 (0.9)	260 (1.7)
Vascular	2 (1.8)	246 (1.6)
Radiology	1 (0.9)	238 (1.6)
Cardiac	5 (4.6)	216 (1.4)
Cardiology	1 (0.9)	165 (1.1)
Thoracic	4 (3.7)	140 (0.9)
Obstetrics	13 (11.9)	128 (0.8)*
Psychiatry	0 (0.0)	125 (0.8)
Pain	0 (0.0)	22 (0.1)
Other minor procedure	0 (0.0)	262 (1.7)
Other major procedure	0 (0.0)	126 (0.8)
Total	109	15,325
Not recorded	1	135

Nitrous oxide

11.39 Table 11.16 indicates that nitrous oxide was used equally frequently in Class A reports of AAGA and in the Activity Survey general anaesthetics.

Table 11.16. Nitrous oxide use in Class A cases and Activity survey general anaesthetics (p = 0.26 for comparison of distribution AAGA vs Activity Survey)

	Class A cases (%)	Activity Survey (%)
Yes	26 (27.7)	4,216 (28.6)
No	68 (72.3)	10,504 (71.4)
Total	94	14,720
Not recorded	16	740

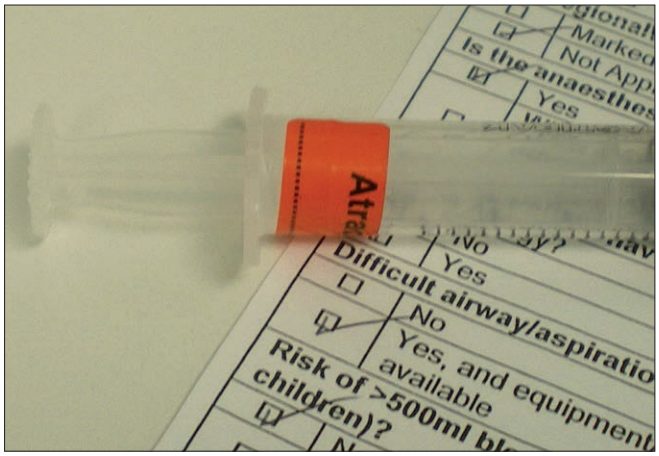
NMBA

11.40 There was disproportionately high use of NMBs in Class A reports of AAGA compared to the Activity Survey general anaesthetics (see Table 11.17), p<0.0001.

Table 11.17. Use of neuromuscular blocking drugs in Class A cases and Activity survey general anaesthetics (p < 0.0001 for comparison of distributions AAGA vs Activity Survey)

	Class A cases (%)	Activity Survey (%)
Yes	4 (3.7)	6,911 (45.8)
No	104 (96.3)	8,163 (54.1)
Total	108	15,074
Not recorded	2	386

Difficult airway management and neuromuscular blockade were both associated with an increase in risk of AAGA



DISCUSSION

11.41 The 110 Class A cases prospectively reported to NAP5 and the >15,000 cases in the Activity Survey represent a considerably larger cohort than most studies in Table 11.1, with the exception of the studies of Domino et al. (1999) and Ghoneim et al. (2009), which were selected case series and without robust comparators.

11.42 The above univariate analysis provides statistical evidence that the following patient and logistical factors are disproportionately over-represented in the Class A cases reports to NAP5 and can therefore be considered risk factors for AAGA:

- Female gender.
- Age (younger adults, but not children).
- Body habitus (obesity).
- Seniority of anaesthetist (junior trainees).
- Previous (but not subsequent) AAGA.
- Time of day.
- Urgency of surgery (emergencies).
- Type of surgery (obstetric, neurosurgery, cardiac, thoracic).
- Use of neuromuscular blockade.

The presence of a locum anaesthetist increased the frequency of AAGA compared with a substantive doctor, though the difference was not statistically significant.

11.43 The data is also supportive of the following as risk factors based on the prevalence of these factors in the NAP5 Class A reports, compared to known incidences in general surgical populations:

- Difficult airway.
- Obesity with difficult airway.

11.44 This analysis provides statistical evidence that the following factors are not risk factors for AAGA:

- ASA.
- Race.
- Use or omission of nitrous oxide.

11.45 This analysis has not provided evidence one way or the other for the following factors, due to lack of robust comparators or incomplete data. The presented data may be useful for others' research:

- Concomitant drugs.
- Excess alcohol.
- Pre-operative anxiety.
- Day of week of anaesthesia.

11.46 This chapter is simply to provide a numerical analysis of the most robust dataset in NAP5. Further aspects of risk factors are discussed in relevant chapters.

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CHAPTER
12

Reports of AAGA after sedation


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HEADLINE

12.1. Approximately one in five of all reports of AAGA that NAP5 received followed intended sedation rather than general anaesthesia. The rate of reports of 'AAGA' following sedation appears to be as high as after general anaesthesia. The experiences of those reporting AAGA after sedation and the psychological sequelae were similar in nature, though perhaps less in severity than reports of AAGA after anaesthesia. Reports of AAGA after sedation represent a failure of communication between anaesthetist and patient and should be readily reduced, or even eliminated by improved communication, management of expectations and consent processes.

BACKGROUND

12.2 NAP5 focuses on patient reports of AAGA. These reports may arise when a patient has not actually received general anaesthesia. It is well recognised that reports of AAGA may occur after sedation (Samuelsson et al., 2007; Mashour, 2009; Kent, 2013). In the study by Samuelsson et al., 5% of patients reporting AAGA had received intended sedation. In Kent's study of self-reports to the ASA awareness registry, 27 of 83 (33%) patients who reported AAGA had received intended sedation: 50% by an anaesthetist and 50% by a non-anaesthetist.

12.3 Indeed one study of >60,000 patients, where patients were asked rather generically 'if they experienced any problems related to anaesthesia', reported no statistically significant difference in the rate of reports of AAGA after general anaesthesia or sedation (0.023% vs 0.03%, p=0.54, relative risk of AAGA in general anaesthesia (GA) vs non-GA 0.74 0.28-2.0 (Mashour, 2009).

12.4 Reports of AAGA after sedation imply two things: first that the patient does not have a full understanding of the intended level of consciousness, and second that the level of consciousness experienced was likely undesirable.

12.5 Esaki et al. (2009) studied 117 patients undergoing regional anaesthesia or 'managed anaesthesia care', and performed a structured interview assessing expected and experienced levels of consciousness. 'Complete unconsciousness' was the state most often expected and also the state most often reported as subjectively experienced. A notable finding in this study was that only 58% of patients reported that their expectations of conscious level for the procedure were set by the anaesthesia provider.

12.6 Reports of AAGA after sedation are not trivial. Kent et al. (2013) compared the experiences and sequelae of patients in the ASA awareness registry whose anaesthesia care was intended to be general anaesthesia with those who had

undergone regional anaesthesia and sedation. The sensations experienced during the event included auditory, tactile and painful sensations and feelings of paralysis. Three quarters of these patients reported distress. Between 25-40% of these patients reported flashbacks, nightmares, anxiety and depression and chronic fear. Although these symptoms were less frequent than in the cohort of patients in the registry who reported AAGA after general anaesthesia, the frequency of long term sequelae did not differ significantly.

Definitions

12.7 There is no colloquial or agreed definition of 'sedation' accessible to patients. The online Oxford English Dictionary (2014) defines sedation (self-fulfillingly) as a verb of action; 'The action of allaying, assuaging, making calm or quiet.', Wikipedia (http://en.wikipedia.org/wiki/Sedation) defines sedation as '*…reduction of irritability or agitation…to facilitate a medical procedure…*' whereas older dictionaries refer to alleviation of pain (Baker, 1956; Onions, 1991).

12.8 The report of the Academy of Medical Royal Colleges defines levels of sedation (consistent with the terms used by the ASA; Table 12.1) as '…drug-induced depression of consciousness, a continuum culminating in general anaesthesia'.

(a) *Minimal sedation* is where the patient responds normally to verbal commands. Cognitive function and physical co-ordination may be impaired, but airway reflexes, and ventilatory and cardiovascular functions are unaffected.

(b) *Moderate sedation* is a state where purposeful responses to verbal commands or light tactile stimulation are maintained. Conscious sedation is a term also applied here, which is a degree of depression of the mental state allowing surgery to proceed where verbal contact is maintained with the patient throughout the period of surgery;

(c) In *deep sedation* the patient responds purposefully only to repeated or painful stimulation; the patient may have depressed respiration and may need a degree of airway support.

12.9 One important limitation of all these definitions in these reports is that sedation is defined by its outcome from the sedationist's perspective, rather than as the actual state of mind the patients might find themselves in as a result of drug administration. Thus from the patient's perspective, responding to verbal stimulation could encompass a wide range of mental states, some of which are acceptable (to the patient) but some unacceptable. Also, these definitions are difficult to use when the conscious level changes rapidly in response to a stimulus or use of a short-acting drug such as propofol (i.e. the definitions lend themselves better to description of a steady state than a dynamic one).

12.10 Indeed the literature highlights different perspectives on sedation. Because analgesia is an important goal, patients frequently misunderstand what sedation is (Chatman et al., 2013) and many want to be completely unaware and have no pain or recall (Subramanian et al., 2005). It is not clearly defined what the purpose or endpoint of sedation is for a caregiver, but first principles suggest that the prevention of awareness of unpleasant aspects of the procedure as well as blunting recall of pain are amongst the important aims (Chatman et al., 2013; Kent et al., 2013). From the patient's perspective, the boundary between sedation and general anaesthesia is obscured (Esaki et al., 2009).

Table 12.1. Continuum of depth of sedation: definition of levels of sedation/analgesia with respect to patient response and intervention required

	Minimal sedation/ anxiolysis	Moderate sedation/analgesia ('conscious sedation')	Deep sedation/ analgesia
Responsiveness	Normal response to verbal stimulus	Purposeful response to verbal or tactile stimulus	Purposeful response after repeated or painful stimulus
Airway	Unaffected	No intervention required	Intervention may be required
Ventilation	Unaffected	Adequate	May be inadequate

12.11 Individual response to sedation may be unpredictable (Gross et al., 2002); a dose of benzodiazepine producing a drowsy state in one person may have little effect in another, render a third unresponsive and a fourth disinhibited. As compared with the relatively predictable relationship between dose and effect for anaesthesia, where the endpoint is unconsciousness, the relationship is far less certain for sedation. Furthermore, this effect in any individual patient may vary over time such that conscious level may very easily vary during a procedure.

Practice

12.12 The Gloucester scoring system has been used by gastroenterologists and is a potentially useful scale to help monitor the quality of sedation as judged by the clinician. (Table 12.2; Valori & Barton, 2007)

Table 12.2. Gloucester comfort score with definitions

1. Comfortable: Talking/comfortable throughout
2. Minimal: One or two episodes of mild discomfort without distress
3. Mild: More than two episodes of mild discomfort without distress
4. Moderate: Significant discomfort experienced several times with some distress
5. Severe: Frequent discomfort with significant distress

12.13 Detailed information about UK sedation practice is limited. We know that there is considerable heterogeneity of the patients and techniques but we know little of what patients experience except perhaps, in intensive care (Sheen & Oates, 2005). Phenomena such as depersonalisation (where the mind finds it difficult to relate to the body) or 'awake dreaming' may be common experiences which may be distressing if they are not anticipated. Even an awake patient undergoing regional anaesthesia may have experiences which are unpredictable (Karlsson et al., 2012).

12.14 Obtaining consent for sedation requires clear communication by the person taking consent so there is a mutual understanding of the process, aims and limitations of sedation (see Chapter 21, Consent).

12.15 Sedation administered by anaesthetists and non-anaesthetists likely differs in both the drugs used and the levels of sedation intended. However the number of episodes of anaesthetist and non-anaesthetist delivered sedation is unknown.

12.16 As compared with non-anaesthetists, sedation administered by anaesthetists tends to involve more potent drugs with lower therapeutic indices, such as propofol combined with opioids or ketamine, because they are effective for a wide range of procedures and have the capacity for rapid control of conscious level. In many countries the role of the anaesthetist-sedationist has expanded with both procedural sedation and 'managed anaesthesia care' (standby care) developing into additional roles for anaesthetists in gastroenterology, cardiac and emergency department settings. The extent to which this trend will be followed in the UK is unknown.

12.17 Current intercollegiate guidelines recommend that non-anaesthetists have special training to administer sedation. Training is the main recommendation from the Academy of Royal Colleges (2013) and NICE (2010).

12.18 Other guidance on sedation, as from Scottish Intercollegiate Guidelines Network (2002); British Society of Gastroenterologists (2003); Royal College of Radiologists, (2003); Royal College of Anaesthetists and Royal College of Surgeons (2007); NICE, (2010); Royal College of Anaesthetists and College of Emergency Medicine (2012), concentrate on the safety and technical aspects of the process. There is an inherent assumption in all these documents that both practitioner and patients know what sedation is; these reports do not at all address the issues of consent and explanation. Only the NICE guideline emphasises the need for clear explanation and what the alternatives might be.

Numbers

12.19 There are few estimates of the numbers of UK patients having different procedures under sedation. The largest groups of adult patients having sedation delivered by non-anaesthetists are probably those undergoing gastrointestinal endoscopy, cardiac angiography and dentistry, but there are no good estimates of practice or number of cases, except perhaps, in the field of endoscopy.

12.20 The older literature contains some data, but it is not known how relevant this is for current practice. A postal survey of endoscopists revealed that upper gastrointestinal endoscopy was commonly performed using benzodiazepine sedation with or without an opioid such as pethidine (Daneshmend et al., 1991). In 1995 a survey of two UK regions by the Audit Unit of the British Society of Gastroenterology gathered data on 14,149 gastroscopies; of these <5% were carried out with

general anaesthesia and ~85% were performed with sedation (Quine et al., 1995). A recent national audit of colonoscopies found that >20,000 colonoscopies were carried out over a two week period (Gavin et al., 2013) giving an annual estimate of ~500,000. This audit found that ~89% of patients underwent conscious sedation using midazolam (with pethidine in 56% and fentanyl in 35%); nitrous oxide was used as the sole agent in ~4%. Less than 1% of patients underwent either deep sedation with propofol or general anaesthesia. The majority of patients were said to be comfortable but ~10% of patients experienced moderate or severe discomfort. In children, the most common procedures are considered to be painless imaging, minor painful procedures, endoscopy and dentistry (NICE, 2010), but the number of children sedated per year for these is unknown.

12.21 Even though the focus of NAP5 is reports of accidental awareness during 'general anaesthesia', for all the reasons described above we judged it important to include patient reports of AAGA that occurred when patients had undergone procedures under sedation but believed they had (or should have) been anaesthetised.

NAP5 CASE REVIEW AND NUMERICAL ANALYSIS

12.22 There were 32 reports (from 31 patients) of AAGA in which sedation was actually the level of consciousness intended by the caregiver. This compares with 141 Certain/probable or Possible (i.e. Class A and B) reports of AAGA. Although the absolute numbers appear small, this means that approximately one of every four or five patients who makes a report of AAGA has not undergone general anaesthesia, but has been sedated.

12.23 Of the 32 reports, ten (31%) were by men and 22 (69%) by women; 12 (38%) reports involved procedures where sedation was provided by clinicians other than anaesthetists. Figure 12.1 shows the histogram of ASA status. The number of cases by specialty is shown in Figure 12.2. Almost all cases were undertaken during the day on weekdays.

Figure 12.1. ASA status of sedation cases

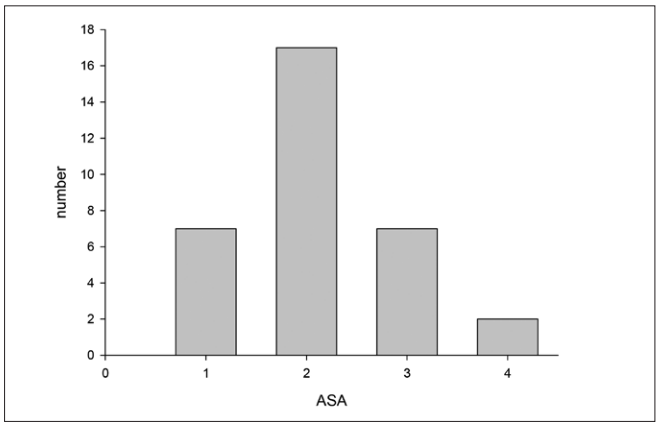
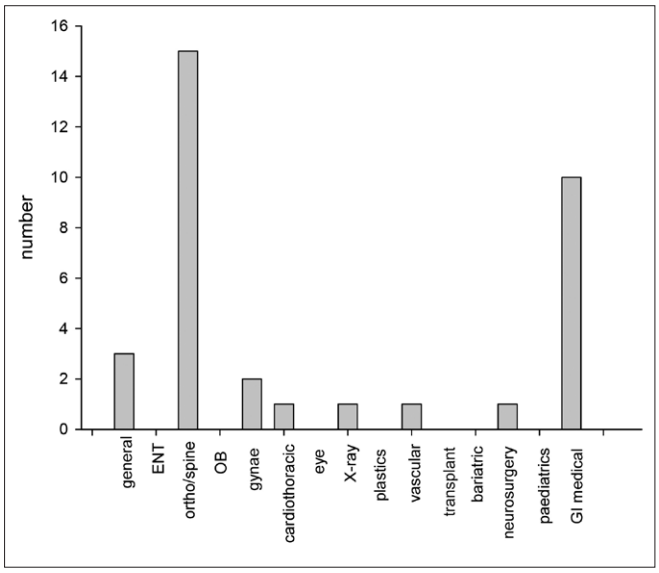


Figure 12.2. Number of sedation cases by specialty. ENT = ear, nose, throat; OB = obstetrics; X-ray = cases in radiology; GI medical = medical gastroenterology



12.24 In terms of the degree of supporting evidence, 26 (81%) of the reports were classified as having 'high' or 'circumstantial' and five (16%) 'plausible'. Evidence no sedation reports were assessed as implausible but one was classed unconfirmed.

12.25 Midazolam was the sole sedative agent in 17 reports (53%), propofol was the sole sedative in 8 cases (25%) and was combined with temazepam or midazolam in a further four cases (12%). In one case there was no record of the drugs used. Opioids were used in 44% of cases as co-agents. Information on the doses used was not available to the Panel.

12.26 The Panel judged that miscommunication, or lack of managed expectations was the main contributory or causal factor in all but six reports (i.e. 81%). In many cases, patients reported that caregivers had specifically used the words they would 'be asleep' or 'light anaesthesia' which they interpreted as being unconscious.

A patient reported hearing hammering during an orthopaedic operation performed with regional anaesthesia and sedation, and was aware that their hands were pulling at the drapes and of people talking and asking the patient to keep still. The patient was not upset or disturbed in any way by this and experienced no pain. However the patient categorically said that the doctor had not explained the possibility of being partially awake or sedated for the procedure.

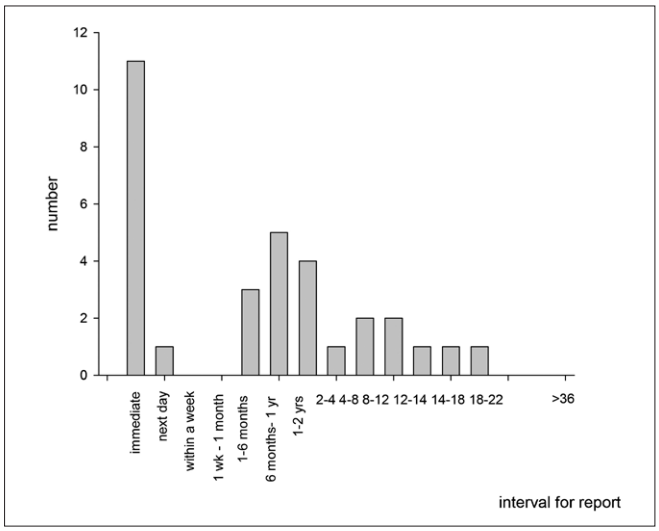
A patient reported: "I woke up and could hear discussion going on around me and the anaesthetist waved his hand in front of me. I was told it would be a light anaesthetic but expected to be asleep. I woke during surgery, heard some hammering and someone saying 'That's a good fit'. I wasn't afraid, and wasn't in pain." The patient expressed surprise, thinking: "This shouldn't be happening should it?" The patient reported the same experience following a second joint replacement a year later. The anaesthetic plan had been regional anaesthesia with sedation for an orthopaedic operation.

12.27 It was surprising that in four cases the patient was explicitly informed that they would not be unconscious and even signed a form of consent to that effect, yet made a report of perceived AAGA.

A young patient underwent endoscopy performed by a non-anaesthetist and found the procedure very distressing being tearful in recovery, saying that they had been informed they would 'be asleep'. The patient had signed a consent form and been provided information that stated: 'Sedation: You will be given a sedative to help you relax, together with some painkillers. This is given via a needle in your hand or arm and will make you drowsy and relaxed but is not a general anaesthetic. You will be able to hear and follow simple instructions during the procedure. You may not remember much about the procedure as the sedation may cause some short term memory loss. However, people often respond differently to the sedation. Some are very drowsy and have little memory of the whole event, whilst others remain more alert'.

12.28 Almost half of the patients made their report immediately after the procedure or the day after. The other patients delayed their report for months or years – the longest delay being 22 years (Figure 12.3).

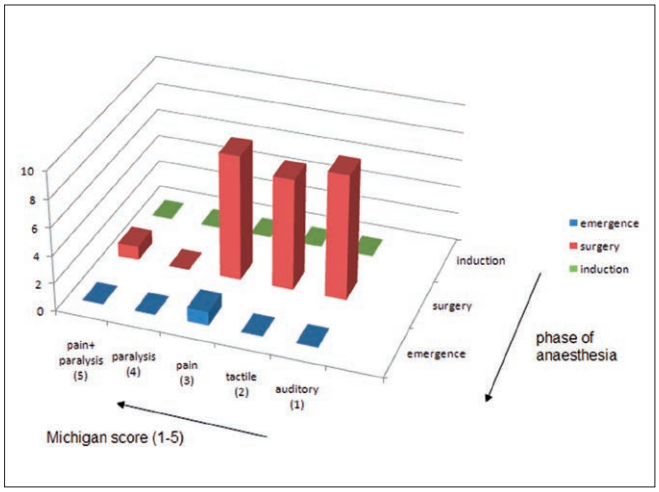
Figure 12.3. Histogram of time interval before sedation cases made a first report of perceived AAGA



12.29 In terms of the experience of the reported AAGA, almost all events arose during the phase of the intervention (or 'surgery') and none at 'induction' (which is perhaps understandable as there is no clear phase of induction during sedation). One report described experiences during the 'recovery' phase. See Figure 12.4.

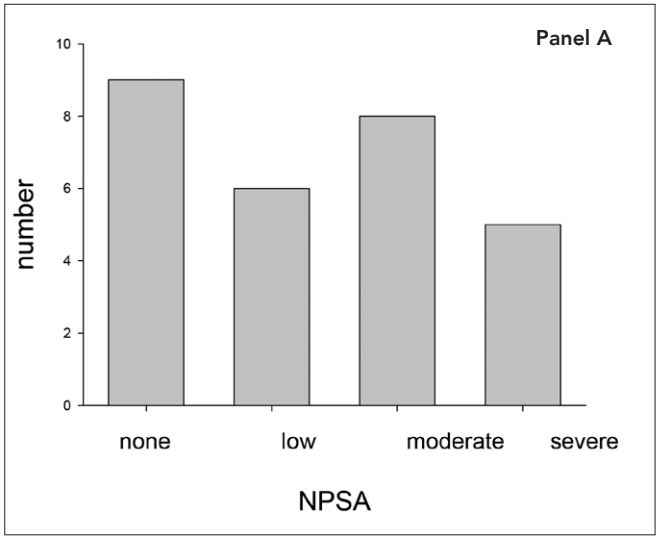
About two-thirds of experiences involved auditory and tactile sensations (i.e. Michigan scores 1 and 2). About a third of patients reported pain, and there was one instance of paralysis plus pain. This last was associated with distress at the time. In total about half the patients (15) reported distress, more so if pain was experienced (8 of the 15).

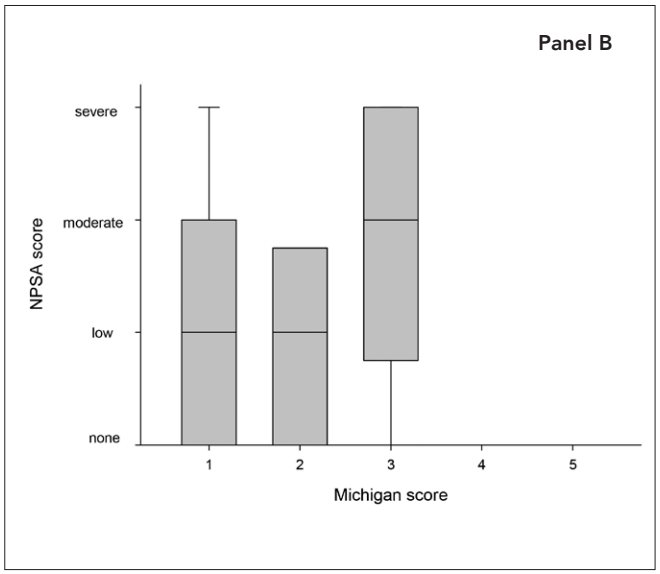
Figure 12.4. Distribution of Michigan scores across the 'phases' of sedation. Michigan 1 = auditory sensations; 2 = tactile sensations; 3 = pain; 4 = paralysis; 5 = paralysis and pain



12.30 The degree of longer term harm as assessed by the modified NPSA score was moderate or severe in about half the cases (Figure 12.5A); i.e. a perception of AAGA had considerable impact on the patients, even when in fact they had received intended sedation. However there was little correlation between symptoms and longer-term sequelae (Figure 12.5B).

Figure 12.5. Panel A: Distribution of impact (modified NPSA score); Panel B: Boxplot of the modified NPSA score by patient experience (Michigan scale)





The patient did not like the drape being over their face, nor the sounds of the saw and drilling which they found unbearable. They bit on their fist to stop themselves screaming 'Stop!' during the procedure. They said there was no one to talk to during the operation or to inform that they were not coping and expected to be 'naturally asleep'.

A patient reported that they woke up in the operating theatre three times while under the anaesthetist's care. They reported being able to see the surgeon cutting into their limb. The anaesthetist asked if the patient wanted to go back to sleep and they said 'Yes'. They woke up a further two times during surgery and during a further anaesthetic procedure. The notes recorded a well-documented plan of 'sedation, spinal and nerve block at end' but the patient stated they were promised they would be completely unaware of the procedure. The patient experienced pain during the nerve block and reported that they were 'mentally scarred' and 'phobic of having any more surgery'. The patient was referred to a psychologist.

DISCUSSION

12.31 Patients may report AAGA despite not having a general anaesthetic. The reasons for this are explored in Chapter 21 (Consent). For those patients who do report AAGA after sedation or regional anaesthesia the experiences are not dissimilar to those reported after AAGA and there may be significant psychological sequelae.

12.32 The data from NAP5 reinforces that from Kent et al. (2013). Using a patient registry that recruits self-referred patients, they found that 27 of 80 AAGA cases in fact underwent sedation (31%). The spectrum of symptoms experienced by these patients was broadly similar to our finding in Figure 12.5B. Kent et al. found the incidence of tactile/ auditory experiences was ~20%; of pain ~10%; and of distress ~80%. However, they reported a higher incidence of paralysis (~25%) and pain with paralysis (~45%). It is unclear why none of our reports also complained of any 'paralysis' from regional anaesthesia.

12.33 Kent et al. (2013) were able to examine in detail the longer term psychological sequelae, with overall 40-50% of patients experiencing a mix of symptoms including anxiety, flashbacks, nightmares, depression and chronic fear. NAP5 methodology did not have the resolution to explore this level of detail, but our finding that about half of patients experienced moderate or severe impact (Figure 12.5B) is consistent with their results.

12.34 These findings emphasise three points:

(a) The importance of investigation of all reports of AAGA to confirm, amongst other things, that general anaesthesia was in fact intended (and/ or expected) by the patient.

(b) The importance of ensuring that both patient and practitioner agree and understand the intended level of sedation when that is intended.

(c) That reports of AAGA after sedation are not trivial and should be managed as other reports.

12.35 From the Activity Survey we estimate that there are ~310,000 anaesthesia-administered cases of sedation (i.e. minimal, moderate or deep sedation) per year. There were 20 reports of AAGA where sedation was administered by anaesthetists. This yields an estimate for perceived AAGA during anaesthetist-administered sedation of ~1:15,500. This seems at least as common as Certain/probable or Possible AAGA reports after anaesthesia (~1:20,000; Chapter 6, Main Results).

12.36 The number of sedation cases by non-anaesthetists is unknown. Gavin et al. (2013) estimated ~500,000 colonoscopies and Quine et al. (1995) ~400,000 sedated gastroscopies. It therefore seems likely that well over 1 million sedation episodes take place in the UK each year, with the vast majority of sedated patients managed by non-anaesthetists. We cannot guarantee that NAP5 detected all reports of perceived AAGA that were made to non-anaesthetists and therefore make no effort to estimate an incidence.

12.37 Such data would be important to explore the speculation that where an anaesthetist is involved, patients automatically have a greater expectation of 'anaesthesia' (i.e. complete unconsciousness) simply because of the job title of the person involved.

12.38 However, Gavin et al. (2013) reported discomfort and pain rates to be ~10% and even if a tenth of these patients expected full unconsciousness and thus report AAGA, this would result in ~500 patients a year perceiving AAGA after sedation for colonoscopy alone. In line with suggestions by Gavin et al. more research is needed on patient experiences after interventions where sedation is undertaken by non-anaesthetists.

12.39 Communication with patients undergoing procedures under sedation could be improved. Terms such as 'we'll give something to make you sleep', or 'you won't be aware of anything' should be avoided as they describe a state of anaesthesia or total amnesia and thus misinform the patient. While the only record a patient has of events is their (fragmented) memory, a written signature provides some reassurance (to all involved) that clear information was originally provided. Most sedation cases are elective so there is ample opportunity for written information to be provided beforehand. This information should, amongst other things, make clear that the patient may retain memory of the procedure. See also Chapter 21, Consent.

Failures of communication were the cause of almost 90% of reports of 'AAGA' after sedation

12.40 The Activity Survey estimates about 500,000 patients underwent procedures awake supervised by anaesthetists, but none of these reported AAGA (i.e. patients who were awake, unlike some sedated patients, did not expect to be fully unconscious).

12.41 Table 12.3 indicates some useful forms of words that help define sedation from the patient's perspective.

Table 12.3. Continuum of depth of sedation: definition of levels of sedation/analgesia with respect to patient response and intervention required

	What will this feel like?	What will I remember?	What's the risk related to the sedation drugs?
Not sedated; awake	I am awake, possibly anxious. There may be some mild discomfort (depending on the what I am having done)	Everything	Nearly zero
Minimal sedation	I am awake and calm. There may be some mild or brief discomfort	Probably everything	Very low risk
Moderate sedation	I am sleepy and calm but remain in control. I may feel some mild discomfort	I might remember some things	Low risk
Deep sedation	I am asleep. I will not be in control	Probably very little	Higher risk. My breathing may slow when I am asleep – and I may need help to breathe – a tube might be inserted into my nose, mouth or (rarely) windpipe. I will need oxygen and special monitoring
Anaesthesia	I am deeply 'asleep' and unable to respond	Very unlikely to remember anything	Higher risk (but the presence of an anaesthetist increases safety). My breathing may slow or stop and my blood pressure and heart rate may fall. I will need a specialist doctor to look after my breathing and support my blood pressure and heart rate I will need oxygen and special monitoring and equipment

RESEARCH IMPLICATIONS

Research Implication 12.1
More collaborative research between anaesthetists and other specialists involved in sedation is needed on patient experience and outcomes after sedation for interventional procedures, especially where sedation is conducted by non-anaesthetists.

Research Implication 12.2
It would be interesting to compare if patient expectations or recollections differ (regardless of information provided) between sedation conducted by an anaesthetist versus a non-anaesthetist.

Research Implication 12.3
Sedation offers a rich research base for the study of retention of information and memory. This is highly relevant for how best to take consent from patients undergoing procedures under sedation.

Research Implication 12.4
NAP5 received no reports relating to instances of patient-controlled sedation. The efficacy and practicality of patient controlled sedation might be a useful avenue for further research.

Research Implication 12.5
The question whether different drugs used in sedation have differential influences on aspects of the experience of recall is amenable to further research? (i.e., do some drugs tend to impair memory while others impair the perception of noise vs touch, etc?).

RECOMMENDATIONS

RECOMMENDATION 12.1

Patients undergoing elective procedures under sedation should be provided with written information well in advance of the procedure. This should emphasise that during sedation the patient is likely to be aware, and may have recall, but that the intention is to improve comfort and reduce anxiety. It should be stressed that sedation is not general anaesthesia.

RECOMMENDATION 12.2

On the day of procedure, sedation should be described again from the patient's perspective, using terminology such as that suggested in Table 12.3 as a guide.

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