

Original Article

Major complications of airway management: a prospective multicentre observational study

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Summary

We conducted an observational study of serious airway complications, using similar methods to the fourth UK National Audit Project (NAP4) over a period of 1 year across four hospitals in one region in the UK. We also conducted an activity survey over a week, using NAP4 methods to yield an estimate for relevant denominators to help interpret the primary data. There were 17 serious airway complications, defined as: failed airway management leading to cancellation of surgery (eight); airway management in recovery (five); unplanned intensive care admission (three); and unplanned emergency front of neck access (one). There were no reports of death or brain damage. This was an estimate of 0.028% (1 in 3600) complications using the denominator of 61,000 general anaesthetics per year in the region. Complications in patients with 'predicted easy' airways were rare (approximately 1 in 14,200), but 45 times more common in those with 'predicted difficult' airways (approximately 1 in 315). Airway management in both groups was similar (induction of anaesthesia followed by supraglottic airway or tracheal tube). Use of awake/sedation intubation, videolaryngoscopy and high-flow nasal oxygenation were uncommon even in the predicted difficult airway patients (in 2.7%, 32.4% and 9.5% of patients, respectively). We conclude that the incidence of serious airway complications is at least as high as it was during NAP4. Despite airway prediction being used, this is not informing subsequent management.

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Introduction

The fourth UK National Audit Project (NAP4) of the Royal College of Anaesthetists [1] (data collection September 2008–August 2009; publication 2011) informed airway management and helped shape the 2015 guidelines of the Difficult Airway Society for the management of failed tracheal intubation in adults [2]. Since then, there have been considerable developments, such as the publication of further airway management guidelines [3–5], increased use

of videolaryngoscopes [6, 7] and introduction of disposable flexible fiberoptic bronchoscopes [8].

In 2016, the authors of NAP4 suggested that, based on a national survey, the 'safety gap' in airway management practice and training had narrowed [9], although there was more to be done. Now, 10 years after the NAP4 data collection period, we wished to revisit airway complications associated with anaesthesia. Our objective was to describe the frequency of airway complications in our local region,

and to assess if they were being managed in accordance with published guidelines. While we intended to follow, as closely as possible, the methods of NAP4, we recognised the possibility that numbers from one region would be considerably lower than NAP4 for the country as a whole. Therefore, to maximise sample size, we extended the inclusion criteria to two other relevant events: airway events in recovery and failed airway management leading to cancellation of surgery on the day. Our wider aim was to identify any key areas for further training and development.

Methods

This project was reviewed by the local ethics committee and the Trust Joint Research Committee who determined that since no patient or healthcare professional identifiable information was involved, no ethical application was necessary. The study was classed as a service evaluation and duly registered locally. Six hospitals were invited to contribute data to the major complications of airway management in Thames Valley (MCAM) study and five agreed to do so. The study was organised both as a data collection period (over a year) and also an activity survey (over 5 days). One hospital was unable to collect data for organisational reasons during the activity survey and so could not continue, leaving four in the study. Individual hospital data were collected by local leads and submitted to a central team for review.

Data for the activity survey were collected during a 5-day period in September 2018 (selected to avoid public holidays; see also online Supporting Information, Appendix S1 for the data collection form). All cases in an operating theatre including obstetric and off-site cases were included. The only exclusions were cases within intensive care units (ICU), such as transfers for imaging, or cases such as airway management in the Emergency Department. The numbers collected were extrapolated to annual figures using the approach described in the NAP5 activity survey [10]. This survey, which was more comprehensive than that which accompanied NAP4, also provided some comparator denominator data against which we mapped results obtained by our survey. We collected data on the conduct of anaesthesia; the types of airway devices used; whether the patients had a 'predicted difficult'; or, in contrast, a 'predicted easy' airway (as judged by the individual anaesthetists). The 5-day case-load was adjusted to reflect under-reporting and estimated for each hospital by the local leads by cross-checking with local operating theatre activity logs. This figure was then multiplied by 50 to reflect a year's activity (including weekends), accounting for national holidays and rounded to the nearest hundred.

Data for the main study of complications were collected from 1 October 2018 to 30 September 2019, and managed by local co-ordinators, who reviewed activity and complications on a daily basis. The data collection form, based on that of NAP4 [1] (see also online Supporting Information, Appendix S2), was submitted for each case as it arose to the study. The study structure meant that, as in NAP4 and other NAPs, the only contact was between the study team and the local co-ordinator. The study team had no knowledge of staff or patients involved in any report. The review panel for each case comprised the study authors, who analysed the information to decide if a reported case was includable. The review panel was based in Oxford, which has six sites, and each of these had its own local co-ordinator, so locally there was distance between the panel and identifiable patient information. In the case where a panellist was involved in a reportable case, the plan was for them to recuse themselves from review of a report. This was not needed.

Triggers for reporting to the study team were that it should be a patient booked for surgery who then developed an airway complication leading to at least one of: death; brain damage; emergency (unplanned) front of neck access (FONA); unanticipated ICU admission due to airway complications; prolongation of ICU stay (due to airway management complications in theatre for patients already in ICU); need for active airway management in the post-anaesthesia care unit (PACU); failed airway management leading to cancellation of surgery on the day. Note that the last two inclusion criteria are over and above those used in NAP4.

Results

Four hospitals returned data for the activity survey – three were district general hospitals and one a tertiary teaching hospital. Individual hospital data are shown in Table 1. The capture rate for each hospital as estimated by local co-ordinators ranged from 83.5% to 97.8%. Across all hospitals during the 5-day period, a total of 1329 patients were recorded out of a total of 1488 estimated patients based on available electronic surgical activity data (mean capture rate 89.3%). This statistic was used to estimate annual rates (see also online Supporting Information, Appendix S1). For the sample size collected (1329 patients; Table 1) and this level of capture rate, the estimated upper limit of 95%CI to the annual estimate is 12% (see also online Supporting Information, Appendix S1 [10]).

The activity survey yielded an estimate of overall volume of activity and provided an estimate of the

Table 1 Activity survey of cases by hospital site and annual case-load estimates. Values are number or proportion.

	Cases during activity survey	Estimated capture rate	Estimated total patients during the study period	Estimated total per year
Hospital A	576	85.1%	677	33,850
Hospital B	448	97.8%	458	22,900
Hospital C	208	83.5%	249	12,450
Hospital D	98	94.2%	104	5200
Total	1329	89.3%	1488	74,400

denominator for the complications. Where appropriate for some of the analysis we needed only to use the actual activity numbers (Table 1, second column) and not the annual estimates; for other analyses we use the annual estimates. Over 80% of cases were performed under general anaesthesia, with the remainder involving regional anaesthesia with or without sedation (Table 2).

For patients under general anaesthesia, the airway devices used are shown in Table 3, as well as comparison with the frequency of use in NAP4 (where the latter were available). A ratio of < 1 in this statistic indicates that the device was used more frequently in NAP4 than in our study. Overall, supraglottic airway devices (SADs) were used slightly more frequently (52%) than tracheal intubation. The LMA® laryngeal mask Classic (Teleflex, Athlone, Ireland), or equivalent, was the most commonly used SAD (27%), but use of the i-gel® (Intersurgical, Wokingham, UK) is five-fold greater in our study compared with NAP4 (21.1% vs. 3.98%).

Airway complications

Twenty-nine patients were reported to the study team, of which 22 were deemed potentially to meet the inclusion criteria and fully reported. Of these 22 patients, 17 occurred in patients in the operating theatre undergoing general anaesthesia. The remaining five were primary emergency airway patients attending the operating theatre via either the Emergency Department or the ward locations where the original airway

deterioration had arisen. These five non-theatre patients were therefore not studied, though they are discussed later in narrative form.

Using the activity survey estimate of 61,000 general anaesthesia cases per year (Table 3), these 17 patients give an overall estimated incidence for major airway complications of 0.028% (approximately 1 in 3600; 95%CI 0.02–0.04%).

The majority of reported airway complications took place in the operating theatre (13 out of 17; 76.5%, 95%CI 50.0–93.2%) as opposed to PACU and most were in elective vs. emergency patients (13 out of 17; 76.5%, 95%CI 50.0–93.2%).

The triggers for making a report were as follows: failed airway management leading to cancellation of surgery (eight); airway management in PACU (five); unplanned ICU admission as a result of an airway problem (without FONA; three); and unplanned emergency FONA (which was then admitted to ICU; one). There were no reports of death or brain damage.

The sex ratio of the 17 patients was nearly equal (Table 4). Most (10 out of the 15 adult patients; 66.7%, 95% CI 38.4–88.2%) were classed as obese or had a predicted difficult airway (13 out of 17; 76.5%, 95%CI 50.0–93.2%). Six of the included patients (35.3%, 95%CI 14.2–61.7%; all predicted difficult airway) were known to have pre-existing head and neck pathology. Table 4 shows the ratio of characteristics in the patients with complications vs. those in the NAP5 activity survey [10] (and, for predicted airway

Table 2 Anaesthetic technique reported within the activity survey. Values are number or proportion.

	Patients during activity survey	Estimated total per year to nearest hundred	Proportion of total patients
GA	1089	61,000	82%
RA alone	185	10,400	14%
RA + sedation	29	1600	2%
Sedation alone	26	1500	2%
Total	1329	74,500	100%

The annual estimate is derived using NAP5 methodology [10] and corrected for an estimated 89.3% capture rate. GA, general anaesthesia; RA, regional anaesthesia.

Table 3 Airway device used for general anaesthesia. Values are number (proportion) or number.

	Activity survey	Annual estimate to nearest hundred	MCAM:NAP4 ratio
SAD	564 (51.8%)	31,600	0.9
LMA laryngeal mask Classic	297 (27.3%)	16,600	0.6
i-gel	230 (21.1%)	12,900	5.3
LMA Flexible	31 (2.8%)	1700	-
LMA Supreme	6 (0.6%)	300	-
Tracheal intubation	463 (42.5%)	25,900	1.1
Tracheostomy	7 (0.6%)	400	1.7
Facemask only	53 (4.9%)	3000	0.9
Awake tracheal intubation	2 (0.2%)	100	-
Total	1089	61,000	-

The proportions are of general anaesthesia patients. A double-lumen tracheal tube was used in seven patients, a nasal tracheal tube in four and a jet catheter in three; otherwise all these are oral tracheal tubes.

SAD, supraglottic airway device; LMA, laryngeal mask airway; MCAM, major complications of airway management in Thames Valley study; NAP4, National Audit Project 4.

Table 4 Characteristics of patients with airway complications. Values are number (proportion).

	Reported cases n = 17	Proportion of cases in NAP5 activity survey (or *our activity survey)	Cases:activity survey ratio
Male	9 (52.9%)	50%	1.1
Age; y			
< 16	2 (11.8%)	12.8%	0.9
16–25	1 (5.9%)	9.0%	0.7
26–35	1 (5.9%)	14.1%	0.4
36–45	2 (11.8%)	12.1%	1.0
46–55	4 (23.5%)	12.2%	1.9
56–65	4 (23.5%)	13.2%	1.8
66–75	2 (11.8%)	13.4%	0.9
> 75	1 (5.9%)	12.0%	0.5
BMI; kg.m ⁻²			
< 25	5 (29.4%)	48.4%	0.6
25–29.9	2 (11.8%)	26.9%	0.4
≥ 30	10 (58.8%)	22.2%	2.6
ASA physical status			
1	3 (17.6%)	38.0%	0.5
2	6 (35.3%)	40.2%	0.9
3	7 (41.2%)	18.7%	2.2
4	1 (5.9%)	2.8%	2.1
Predicted difficult airway	13 (76.5%)	6.8*%	11.3

The proportion of cases is estimated using data from the NAP5 activity survey [10], or in the case of predicted difficult airway from our activity survey. Body mass index data were not collected for children but were assumed to be < 25.

difficulty, vs. our own activity survey). The characteristics that were over-represented in the complications group were a predicted difficult airway (ratio 11.3), followed by obesity (ratio 2.6) and comorbidities (ASA 3/4 vs. ASA 1/2 ratio

approximately 2.1). The 45–65 y age group was also over-represented (ratio 1.8–1.9) as compared with other groups. There were no complications reported from obstetrics for the study period.

Management of the airway complications

Table 5 shows how patients were managed in the activity survey and in the complications group, categorised by predicted difficulty of airway. In the activity survey week, an estimated 74 out of 1089 general anaesthesia patients (6.8%, 95%CI 5.4–8.5%) were 'predicted difficult' airways. This translates to an estimate of approximately 4100 predicted difficult airway patients over a year of activity. With 13 airway complications arising in the 'predicted difficult' group, this makes the incidence of complications 0.32% (95%CI 0.17–0.54%) in this group (13 out of 4100; or approximately 1 in 315). Using the same analysis, the estimated incidence of airway complication with a predicted easy airway is approximately 0.007% (95%CI 0.0–0.002%) approximately 4 out of 56,900; or approximately 1 in 14,200). We estimated that patients with a predicted difficult airway have approximately 45-fold the risk of suffering airway complications compared with predicted easy airway patients.

The low absolute numbers in the group with airway complications made it difficult to undertake ratiometric comparisons of management methods. While SAD use was most common in patients with predicted easy airways (activity survey), all predicted easy patients who experienced a serious complication underwent tracheal

intubation after induction of anaesthesia as the primary airway plan. Of patients predicted difficult in the activity survey, the most popular management plan was tracheal intubation after the induction of anaesthesia (59 out of 74 patients; 79.7%, 95%CI 68.8–88.2%) and awake intubation was infrequent (2 out of 74 patients; 2.7%, 95%CI 0.33–9.4%). Four out of 74 patients (5.4%, 95%CI 1.5–13.3%) underwent planned tracheostomy. Broadly similar proportions of these types of management pertained in the group that suffered complications, with the exception that none of those who suffered complications underwent planned tracheostomy.

Table 5 is restricted to data for patients undergoing general anaesthesia. In the activity survey week, 5.1% (95% CI 1.4–12.6%) of patients (4 out of 78) with a predicted difficult airway were managed using regional anaesthesia. This is in contrast to 214 out of 1251 (17.1%, 95%CI 15.1–19.3%) of patients without a predicted difficult airway who were managed using regional anaesthesia.

Figure 1 illustrates the steps in airway management in the 17 patients with airway complications and in the online Supporting Information (Table S1) details the patients in anonymised format. In 12 out of the 13 patients with predicted difficult airway (92.3%; 95%CI 64.0–99.8%), tracheal intubation after the induction of anaesthesia was the primary airway plan, with direct laryngoscopy

Table 5 Management of cases by predicted airway difficulty.

	Group with complications n = 17	Activity survey week	Estimated annual denominator from activity survey data	Complication: activity survey ratio
Predicted easy airway	4 (23.5%)	1015 (93.3%)	56,900	0.25
SAD	0	555 (54.7%)	31,100	-
Tracheal intubation	4 (100.0%)	404 (39.8%)	22,700	2.5
Tracheostomy	0	3 (0.3%)	200	-
ATI	0	0	0	-
Facemask	0	53 (5.2%)	3000	-
HFNO	0	14 (1.4%)	800	-
Videolaryngoscopy	1 (25.0%)	28 (2.8%)	1600	8.9
Predicted difficult airway	13 (76.5%)	74 (6.7%)	4100	11.4
SAD	1 (7.7%)	9 (12.2%)	500	0.6
Tracheal intubation	9 (69.2%)	59 (79.7%)	3300	0.9
Tracheostomy	0	4 (5.4%)	200	-
ATI	3 (23.1%)	2 (2.7%)	100	9.6
HFNO	2 (15.4%)	7 (9.5%)	400	1.6
Videolaryngoscopy	4 (30.8%)	24 (32.4%)	1300	1.0

The first column shows the frequency of management types in the group with complications. The second column shows the frequency of management types in the activity survey. The proportions are of the sub-groups (predicted easy or difficult). The final column shows the ratio between cases and activity. High-flow nasal oxygenation data include this technique used with other airway management techniques, and not instead of them.

SAD, supraglottic airway device; ATI, awake tracheal intubation; HFNO, high-flow nasal oxygen.

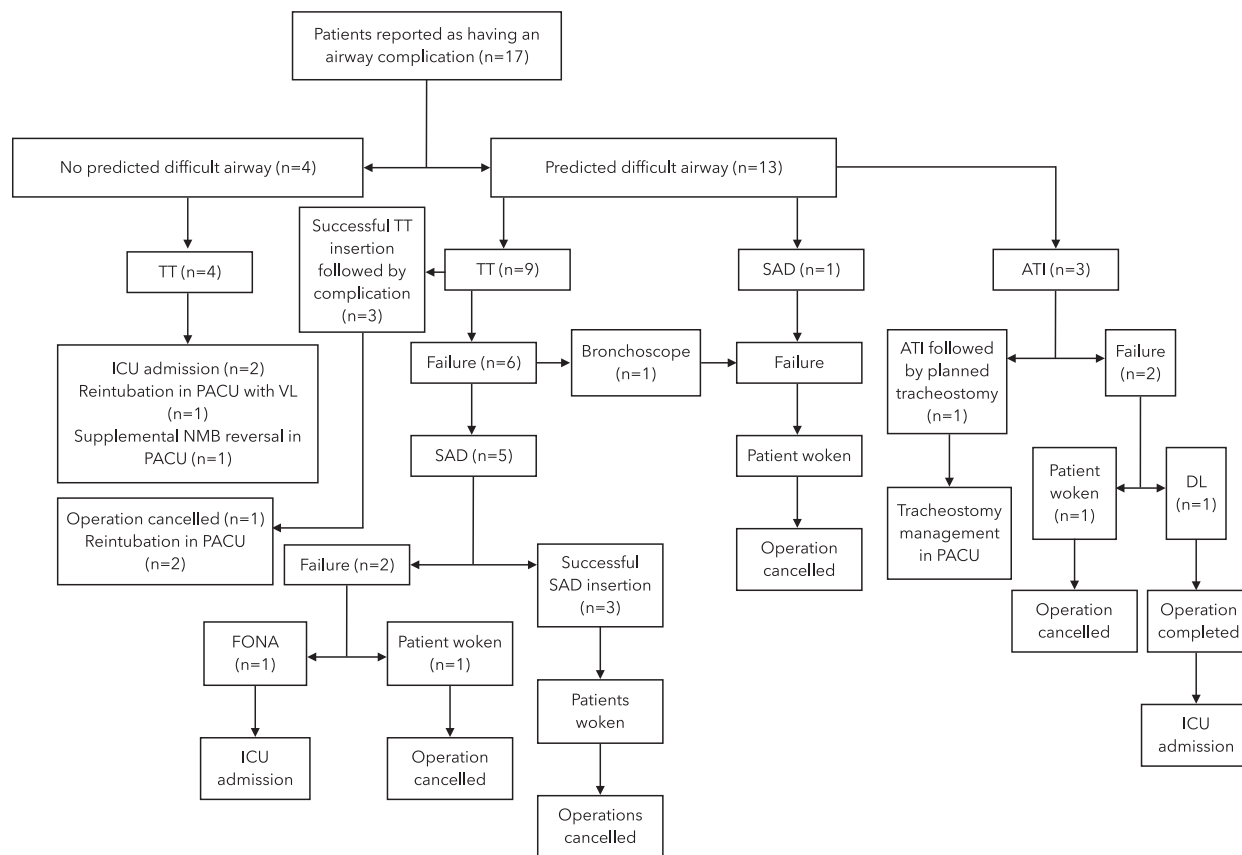


Figure 1 Sequential management of the 17 cases of airway complication. ATI, awake tracheal intubation; DL, direct laryngoscopy; FONA, front of neck access; ICU, intensive care unit; PACU, post-anaesthesia care unit (recovery); SAD, supraglottic airway device; TT, tracheal tube.

planned in nine patients (69.2%; 95%CI 38.6–90.9%) and videolaryngoscopy in four (30.8%; 95%CI 9.1–61.4%). This last was also used in an attempt to rescue six patients where direct laryngoscopy had failed, but videolaryngoscopy also failed. Supraglottic airway device rescue was attempted in five of the patients where direct- or videolaryngoscopy failed and succeeded in providing oxygenation in three. Videolaryngoscopy was attempted in six of the failed intubations and was unsuccessful in each case. Awake tracheal intubation was attempted in three patients (23.0%; 95%CI 5.0–53.8%) but succeeded in securing the airway in only one. There were no cases of surgical cricothyrotomy.

Narrative cases

Five patients were reported to the study team but not studied in quantitative analysis as they were cases of primary airway deterioration outside the operating theatre. Three of these patients presented to the emergency department with stridor and were transferred for emergency airway management. In one patient, awake tracheal intubation was

attempted but was unsuccessful, culminating in successful surgical tracheostomy. In another patient, tracheostomy under local anaesthesia was attempted. This failed due to the loss of the airway through over-sedation, with the airway eventually being secured by the surgeon using direct laryngoscopy. In the last of these patients, direct laryngoscopy was attempted but was unsuccessful, leading to surgical tracheostomy. All these patients were admitted to ICU.

The fourth of these five patients had undergone previous head and neck surgery with radiotherapy and deteriorated on the ward with complete airway obstruction. The anaesthetist attending the peri-arrest call recognised the need for immediate FONA and performed cannula cricothyrotomy, as the only available technique, restoring oxygenation and the patient was transferred to the operating theatre for a surgical airway.

The last of these five patients had an existing stoma following a previous laryngectomy but had features of partial stoma obstruction including pain and swelling around the speaking valve. The patient was taken to the

operating theatre for exploratory surgery. There was substantial bleeding around the stoma and the patient became hypoxaemic and difficult to ventilate. Bronchoscopy was performed which found a blood clot at the carina. This was evacuated and ventilation and oxygenation restored. The patient was transferred to ICU postoperatively.

Discussion

A key finding of our study is an overall incidence of major airway complications of approximately 1 in 3600 general anaesthetics, which is over six times that cited in NAP4 (1 in 22,000) [11]. However, when PACU cases and cancelled operations, which were not included in NAP4, are excluded, our estimate is 1 in 15,000 which is still higher than NAP4. The data do not suggest to us any significant decline in the incidence of airway complications, despite the extensive training, guidelines and new equipment that have been introduced since NAP4.

The overall incidence of a predicted difficult airway of 6.8% (activity survey) seems high but broadly within ranges previously cited [12–14]. Our data may be skewed by inclusion of a large tertiary head and neck centre, or because we specifically asked if a difficult airway was predicted. Only in 28 out of 1329 (2.1%; 95%CI 1.4–3.0%) patients in the activity survey week was the airway difficulty/ease not documented, all cases of regional anaesthesia. This suggests, contrary to NAP4 recommendations, the airway may be overlooked when planning regional anaesthesia.

While our study had the advantage of being multicentre, over half of our reported cases of airway complications (52.9%) took place in a tertiary hospital. This bias, more than in NAP4, may contribute to an overestimation of complications. Although there was high compliance with data collection, we did not directly include weekend work in the activity survey (only indirectly via the estimation method). This led to wider confidence intervals to the denominator data (12%) than would have arisen with a larger sample size. Also, because fewer cases are undertaken at weekends, we therefore overestimated the denominator activity – and hence potentially underestimated the incidence of complications. Notwithstanding the tertiary hospital bias referred to above, this underlines our conclusion that the true incidence of complications was no lower than reported by NAP4, and was probably higher.

Our data reveal that the manner in which difficult airways, even when predicted, were approached differs little from how predicted easy airways were managed, for example induction of anaesthesia first, followed by SAD or

tracheal intubation – with the slight difference that in predicted difficult airways, tracheal intubation was more frequent (Table 5). The fallback was to follow failed intubation guidance (Fig. 1) [2, 15]. However, 4 out of the 17 patients (23.5%; see also online Supporting Information, Table S1) indicate five tracheal intubation attempts, contrary to these recommendations.

Nevertheless, this approach seemed to work, up to a point, in the four cases of unanticipated difficult airway (i.e. originally predicted easy airway; Fig. 1). Reassuringly, the overall incidence of serious complications where an airway was predicted as easy was very low at 1 in 14,200 (Table 5). Even if the act of prediction is deemed inaccurate (in the sense that there is over-prediction of a difficult airway with most turning out to be easy [16]), our data underline the importance of using a binary approach to predicting the easy vs. difficult airway in the first place [17]. In those airways classified as 'easy' (i.e. no concerns as to difficulty) then, regardless of how this is done, a complication is extremely unlikely. In fact, since two out of the four patients in this group were re-intubations in PACU, the true incidence of in-theatre-related airway complications in this group is closer to 1 in 30,000 (Table 5). Our methods did not, of course, capture those predicted easy cases that turned out to be unexpectedly difficult but were managed in a way that did not lead to serious complication. The true incidence of 'actual difficult airway', as opposed to 'predicted difficult airway', may have been higher than our data indicate.

However, this standard approach ('anaesthesia induction followed by SAD/tracheal intubation') is clearly less effective for the airways predicted as difficult and the serious complication rate in this group of approximately 1 in 315 is very high. Specific techniques designed to address the difficult airway include videolaryngoscopy, awake tracheal intubation and high-flow nasal oxygen, but each of these was used in only a minority of the predicted difficult cases in the activity survey (32.4%, 2.7% and 9.5%, respectively). The under-use of videolaryngoscopy in this group is especially surprising given that it increases the chance of successful intubation [18]. Deficiency in airway training has been noted elsewhere [19], but equipment availability may be an explanation, as perhaps also for under-use of HFNO. Equipment availability is an unlikely explanation, however, for scarce use of awake tracheal intubation since immediate access of fibrescopes for emergency use has long been recommended [20] and is now embedded in guidelines [5], including minimal monitoring guidance [21]. Surveys indicate that 99% of UK hospitals had access to a fibrescope in 2015 (vs. just 33% with access then to a videolaryngoscope) [22]. The high

proportion of failure of awake tracheal intubation (Table 5) may be indicative of lack of familiarity or training [5]. An alternative possibility is that not all patients were judged amenable to awake tracheal intubation (e.g. with limited utility in upper airway obstruction or haemorrhage) [23].

One conclusion from our analysis is that it is pertinent to test the following hypothesis: if the incidence of serious complications from airway management is to improve, an approach different from 'standard anaesthesia induction followed by SAD/tracheal intubation' should be adopted for patients predicted as difficult. Note that this is not affected by whether the act of predicting difficulty was accurate or not. The 'real-world' application of prediction – with all its shortcomings – results in two groups of patients with strikingly different outcomes. In this regard, others have proposed tailored approaches (which include fiberoptic intubation, careful preoxygenation and videolaryngoscopy) applied to predicted difficult vs. predicted easy airways, with encouraging results in clinical outcomes [24, 25].

Although compliance with data collection was high, we were concerned to learn of one death as a serious complication of airway management, which should have been reported as the 18th case in our dataset. (This would have made our incidence even higher than we report, as compared with NAP4.) The local co-ordinator explained that the team did not wish to report this due to the sensitivities involved. While this frank admission from a participating centre greatly limits the veracity of our data, it also strengthens the conclusion that there are significant improvements that need to be made in the management of patients with known or predicted difficult airways, and also that considerable learning from the examination of complication cases requires more open and neutral, non-judgemental discussion.

Our data show that the act of predicting the airway usefully separates patients into two broad groups with strikingly different outcomes. In those with a predicted easy airway, a standard approach of 'anaesthesia induction followed by SAD/tracheal intubation' very rarely results in serious airway complications (just 1 in 30,000 for in-theatre events). In those with a predicted difficult airway, this standard approach results in serious airway complication 45 times more frequently (approximately 1 in 315). Contrary to previous suggestions that the 'safety gap' may have narrowed after NAP4 [9], we do not see this translated effectively into a reduction in airway complication rates. Notably, airway management is rarely tailored to the predicted airway challenge, and specific techniques developed since NAP4 are under-employed, such as videolaryngoscopy, awake tracheal intubation and HFNO.

Training in techniques, equipment as well as human factors will be key [26] and the role of the recently introduced DAS Airway Safety Leads will be central to any strategy [27]. Specifically, a working hypothesis for future similar audits should be that the incidence of complications will only decline with the increased use of dedicated airway techniques to manage the predicted difficult airway.

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Supporting Information

Additional supporting information may be found online via the journal website.

Appendix S1. Data collection form for activity survey.

Appendix S2. Airway complication data collection form.

Table S1. Narrative summary of the 17 included cases.