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Review Article

Airway management research: a systematic review

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Summary

Recent controversy regarding the ethics of conducting airway research in patients led to disagreements concerning the value and frequency of manikin-based investigation. However, no formal examination of the methodology of airway research has been undertaken. We, therefore, performed a systematic bibliometric review of airway management research to describe the conduct, quantify the subjects (patient vs. manikin vs. other), assess the reported outcomes and map global trends. We retrieved 1505 relevant studies published between 2006 and 2017, together recruiting 359,648 subjects, of which 341,233 were patients, the remaining being volunteers or subjects managing manikins, human cadavers, animals or bench models. There were 701 randomised controlled clinical trials (46.6%), 83 non-randomised experimental clinical trials (5.5%), 298 observational studies (19.8%) and 423 non-patient studies (28.1%). A total of 1082 studies (71.9%) were patient studies and 322 were manikin studies (21.4%). The total annual number of airway management studies increased over time, as did the annual number of patient studies, but there was no significant increase in the annual number of manikin studies over time. Of the patient studies, subject baseline characteristics were most likely to be ASA status 1–2 (n = 531, 49.1%), populations were most often elective surgical patients (n = 918, 84.8%) and the most common interventions studied were tracheal intubation (n = 820, 54.4%) or supraglottic airway device insertion (n = 257, 17.1%). There was a total of 77 different primary outcomes used in the included studies, the most commonly reported being success rate and procedure time. By understanding how and what has been previously studied these data can be used to form the basis for future priority setting exercises, core outcome set development, and could inform strategy on the future directions of airway management research.

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Introduction

There has been a recent drive to improve the safety, efficacy and ethics of airway management research [1–3]. However, there is disparity between the perceived value of the different study 'subjects' (i.e. patients vs. manikins or cadavers or animals) [4–6]. The process of setting up a clinical trial in humans is complex and challenging. In particular, securing funding and ethical approval, patient screening, recruitment and retention all require significant investment, so alternative study designs to clinical trials, such as manikin studies, are often sought [6]. Moreover, in clinical trials, the relatively low incidence of clinically important outcomes (e.g. failed intubation or death) as well as the ethical considerations in investigating novel interventions, present further potential barriers. Manikin studies have found a place in airway management research with the ability to overcome some of these challenges [7–10].

There have been a number of patient studies published where difficult tracheal intubation has been simulated in an otherwise 'normal' airway [11–14]. The ethical acceptability of this has been questioned, leading to the development of consensus guidelines on airway research ethics (CARE) [2], which seek to restrict the number of attempts at securing the airway, limiting participants to only ASA status 1–2 and excluding patients with potentially difficult airways. Since these guidelines were predicated in part on an assumption that there was an excessive number of manikin studies, their relevance and 'consensus' nature have been questioned in disagreements in the literature [2, 4, 5].

This exchange of correspondence led us to examine the true proportion of manikin studies in the recent airway management literature. In doing so, we also wished to assess the methodologies that have been employed in airway studies, including an analysis of end-points that have been used. In turn, we can use these data to map the geographical distribution of research, and the results of this review can be used as a basis for future priority setting exercises, determine core outcome set development and to guide future airway management research [15, 16].

Methods

This systematic review adhered to the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) recommendations [17]. A broad electronic database search was performed with the assistance of an information specialist, of MEDLINE, Embase and Web of Science. We applied medical subject headings, controlled vocabulary terms, text words and their variants relating to the primary question of interest. These included, but were not limited to: airway control; airway management; airway devices; anaesthesia; bag-mask ventilation; cricothyroid; fibreoptic, intubation; laryngoscopy; oxygenation; supraglottic airway devices; ventilation and videolaryngoscopy (Appendix S1). These search terms were used individually and in assorted permutations. The search was not limited to language. To ensure contemporary relevance of the data, the search was restricted to studies published between 1 January 2006 and 31 December 2017. Abstracts and other non-full–text original research articles were excluded.

We sought full-text published manuscripts and utilised the patient, intervention, comparator, outcome (PICO) approach to assess eligibility. The population of interest included: human patients (≥ 18 years); manikins; simulation studies; volunteer studies; bench studies and technological studies. Studies of paediatric (< 18 years) or neonatal patients were excluded, as airway management is sufficiently divergent from adult airway management in terms of anatomy, physiology, pharmacology and clinical management strategies. Any study involving airway intervention was deemed relevant, including tracheal intubation, supraglottic airway device (SAD) insertion, bag-mask ventilation, front-of-neck access, oxygenation strategies, diagnosis and airway assessment, bronchoscopy for intubation, or pharmacological interventions during airway management. We set no specific limitation or requirement for comparators or outcomes to be reported on included studies. Study designs suitable for inclusion were prospective studies, including observational patient studies, experimental patient studies (either randomised or non-randomised clinical trials) or prospective non-clinical trials (e.g. manikin, bench, simulation) [18]. Systematic reviews, editorials, case reports or retrospective case series/studies were excluded.

All authors performed title and abstract screening, then subsequently retrieved full-text manuscripts and examined them for eligibility. In cases of uncertainty or disagreement regarding study inclusion or exclusion, consensus was sought among all authors. Due to the heterogeneity in included study designs, risk of bias assessment was not performed, and was, therefore, not a factor in determining study inclusion. Only English language full-text manuscripts were included.

Studies meeting inclusion criteria were divided between all authors and data were independently extracted on to a standardised Microsoft Excel 2016 for Mac (Microsoft Inc., Redmond, WA, USA) spreadsheet. Data included study characteristics, primary outcomes reported, patient baseline characteristics for clinical studies, airway ease/difficulty and operator attributes.

The country of origin was defined as the country from which most subjects were recruited. Study design was defined as stated above. The intervention of interest was defined as the primary intervention examined (e.g. intubation), whereas the device category referred to the device that was being applied to analyse each intervention (e.g. direct laryngoscope or videolaryngoscope). The setting of investigation was categorised as: operating theatre; emergency department (ED); intensive care unit (ICU); pre-hospital, bench; simulation; ward or other. Studies could have multiple settings of investigation (e.g. ED and ICU). The number of subjects recruited from each study either reflected the number of patients recruited, if patients were the subject of investigation, or the number of operators recruited (e.g. number of anaesthetists). Subjects were explicitly distinguished, reported and analysed as either patients, volunteers or operators of different backgrounds managing manikins, human cadavers, animals or bench models. Primary outcomes were defined as: (1) the outcome stated to be primary in the study hypothesis; (2) the outcome stated to be primary in the methodology or (3) the outcome used to conduct power analysis. Primary outcomes were categorised into broad groups, with heterogeneous metrics within each group. For example, success rate could pertain to successful intubation, successful ventilation or successful placement of a SAD. This allowed a broader understanding of the themes of primary outcomes of interest. We extracted patient baseline characteristics from patient studies, including: ASA physical status; the urgency of operative or airway intervention; the type of patient recruited (e.g. head and neck surgery, obese patients) and the category of airway (no difficulty predicted, predicted difficult, simulated difficult). The primary specialty of airway operators was also extracted, which could be anaesthesia, emergency medicine, critical care, other physicians, non-physicians (e.g. nurse anaesthetists, nurses, paramedics), students (e.g. medical students, nursing students) or a range. The experience of operators was defined as experienced, inexperienced or a range. Experience was determined by whether individual manuscripts defined operators as experienced or not.

Descriptive statistical analysis was performed using SPSS® for Mac, version 24.0 (SPSS® Inc., Chicago, IL, USA). Correlations were assessed using Spearman's rank correlation co-efficient (r), and the Chi-square test was used to compare categorical variables. A p value of < 0.05 was considered statistically significant.

Results

After eliminating duplicates, 82,093 records were screened, of which 78,709 were excluded. The remaining 3384 full texts were examined for eligibility, leaving 1505 studies included in our data analysis (Fig. 1, Appendix S2). A total of 359,648 subjects were recruited, of which 341,233 were human patients.

There was an increase in the annual number of prospective airway management trials over the study period (number vs. time: $r = 0.916$, $p < 0.001$; Fig. 2). Publications emerged most frequently from India, the USA, Japan and Korea (Table 1), with the most patients recruited to studies from the USA, Japan and France (Fig. 3, [19]). Airway management studies were most frequently published in *Anaesthesia*, followed by the *European Journal of Anaesthesiology* and the *British Journal of Anaesthesia* (Table 1).

Of the 1505 published airway studies, there were 701 randomised controlled clinical trials (46.6%), 83 non-randomised experimental clinical trials (5.5%), 298 observational studies (19.8%) and 423 non-patient studies (28.1%) (Fig. 4).

The subjects of investigation were human patients in 1082 studies (71.9%), manikins in 322 (21.4%), human cadavers in 39 (2.6%), volunteers in 17 (1.1%), bench investigations in 17 (1.1%), animal in 16 (1.1%) and mixed subjects in 12 studies (0.8%, Fig. 4). There was an increase in the annual number of patient studies over time ($r = 0.942$, $p < 0.001$), but no increase in the annual number of manikin studies ($r = 0.557$, $p = 0.060$, Fig. 2).

In the 1082 patient studies, 531 (49.1%) only included patients who were of ASA physical status 1–2, 229 (21.2%) recruited patients of ASA physical status 1–3, 46 (4.3%) included patients of ASA physical status > 3, whereas 276 (25.5%) trials did not explicitly state ASA inclusion criteria. Elective patients were recruited to 918 (84.8%) airway management studies, both elective and emergency patients in 19 (1.8%), emergency only patients in 92 (8.5%) and 53 studies (4.9%) did not disclose the urgency of the patients recruited. Four-hundred and sixty-five trials (43.0%) recruited a range of patients, but 73 (6.7%) recruited only patients having head and neck operative interventions, 47 (4.3%) having gynaecological interventions, 30 (2.8%) having general surgery, 28 (2.6%) having thoracic surgery and 28 (2.6%) trials investigating obese patients. In patient studies, investigators recruited patients who were not predicted to have difficult airways in 546 studies (50.5%), those who had predicted or known difficult airways in 115 studies (10.6%) and 183 trials (16.9%) had a range of airway difficulties. In 202 studies (18.7%), airway difficulty was either undefined or irrelevant. Researchers simulated difficult airway using a range of techniques in 36 studies (3.3%), including strategies such as application of a cervical collar or deliberately producing grade 3 or 4 Cormack–Lehane views. A total of 351 studies (32.4%) recruited only ASA physical status 1–2 patients who had no predicted or simulated airway management difficulty. There was a median (interquartile range [range]) number of patients of 87 (54–149 [6–50,000]), recruited to each clinical trial.

Across all studies, the intervention of interest was tracheal intubation in 820 studies (54.4%), SAD placement in 257 trials (17.1%) and drug-related interventions in 99 studies (6.6%, Table 1). The most commonly investigated laryngoscopes were the Macintosh direct laryngoscope, GlideScope® (Verathon, USA), Airtraq (Prodol Medica, Spain) and C-MAC® (Karl Storz SE & Co. KG, Germany) videolaryngoscopes. These were used in 414, 172, 101 and

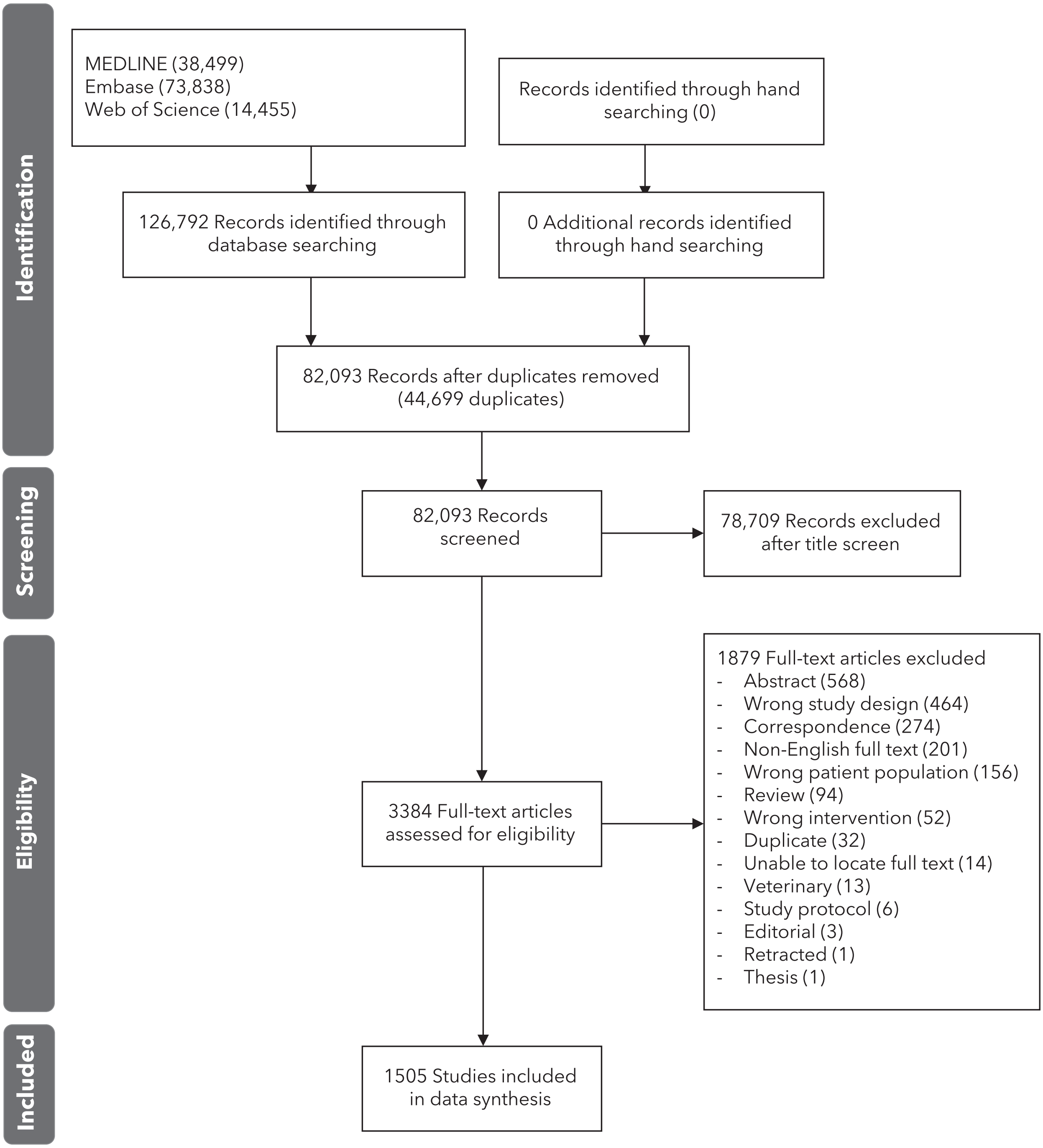

Figure 1 PRISMA flow diagram of studies identified, screened and included in this systematic review.

84 studies, respectively. The most commonly investigated SADs were the LMA classic, i-gel™ (Intersurgical, UK), ProSeal LMA laryngeal mask™ (Teleflex Medical, USA) and LMA laryngeal mask Supreme™ (Teleflex Medical), used in 152, 112, 99 and 71 studies, respectively (Table 1). Front-of-neck access (FONA) was the intervention of interest in 48 studies (3.2%) and patients were the subjects in 12 of these studies (25%), the remainder comprising manikins, cadavers, bench and animal investigations.

There was a total of 77 different primary outcome categories across all studies, with 66 different outcomes in patient studies (Fig. 5), and 35 in non-patient studies.

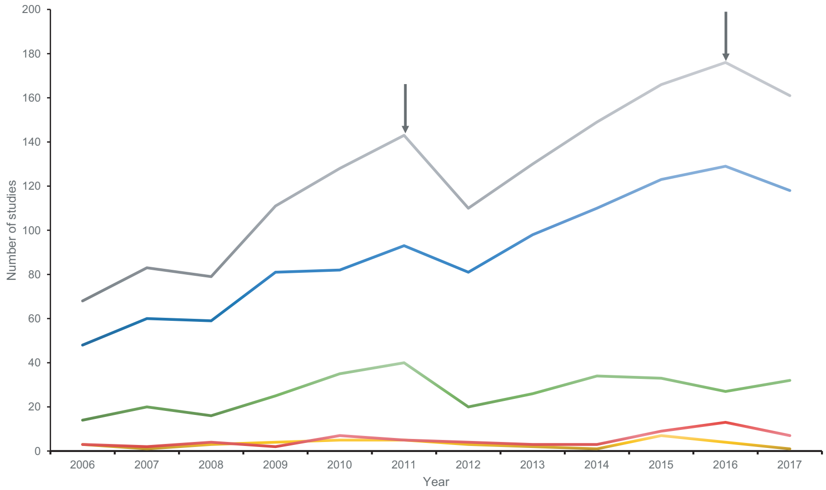

Figure 2 Total number of prospective airway management studies (grey line), patient studies (blue line), manikin studies (green line), cadaver studies (yellow) and other subject studies (red) annually since 2006. Grey arrows represent year of publication of ADEPT in 2011 [1] and CARE Guidelines in 2016 [2].

Across all studies (n = 1505), the primary outcomes were various metrics for success rate in 413 trials (27.4%), different measures for procedure time in 341 (22.7%), oxygenation or ventilation-related parameters in 84 trials (5.6%) and haemodynamic parameters in 74 trials (4.9%, Table 1, Fig. 5). Patient-reported outcomes, either acceptability, comfort or tolerance of airway management interventions, were reported as primary outcomes in seven trials, whereas 18 different clinical safety primary outcomes were reported in 64 studies (Table 2).

Participants who were performing airway interventions were anaesthetists in 1113 studies (73.5%), a range of emergency medicine, critical care and pre-hospital physicians in 122 studies (8.1%), students in 77 trials (5.1%), non-physicians in 74 trials (4.9%), a range of physicians in 45 trials (3.0%), a range of both physicians and non-physicians in 40 studies (2.7%) and 24 trials (1.6%) either did not define the participants or were not relevant to the study. The remaining 10 trials (0.6%) included participants from a range of backgrounds, such as military personnel, astronauts and lifeguards (Fig. 6).

Of the 1082 patient studies, 982 trials (90.8%) assessed airway management interventions in the operating theatre environment, 40 studies (3.7%) in the pre-hospital setting, 28 (2.6%) in ED and 23 (2.1%) in ICU, with the remaining being performed in a range of other settings.

Participants were defined as experienced in 723 studies (48.0%), inexperienced in 228 studies (15.1%), had a range of experienced and inexperienced participants in 186 (12.4%), with the remaining 368 studies (24.5%) either not defining the experience level or not being relevant to the study. Of note, patient studies were more likely to have experienced over inexperienced operators (627 vs. 53), compared with manikin studies (72 vs 150, $p < 0.001$).

Discussion

This review is probably the most thorough analysis of airway management research to date. The data we report provide a benchmark on methodology and end-points used and demonstrate the geographical distribution of airway management research. We found that manikin studies accounted for more than a fifth of airway management trials, which is in stark contrast to that suggested by Cook et al. who reported that manikin studies only account for < 3.5% of studies [4]. We included 1505 trials, whereas Cook's data were based on 33,500 studies. Cook et al. did not provide their search strategy, but our experience leads us to suggest that their denominator may have included studies not directly relevant to airway management [5]. Furthermore, we only sought prospectively designed studies using robust search methodology. Equally we cannot agree with the suggestion of Irwin and Ward that manikin studies are disproportionately represented in airway studies. It is likely that Cook et al. underestimated the proportion of manikin studies, whereas Irwin and Ward may have over-represented these [4,5].

Over the past 10 years there has been a trend of steadily increasing numbers of patient studies published each year. Although the annual number of manikin studies has remained static during this time period, this has resulted in a reduced proportion of manikin studies on a yearly basis.

Table 1 The 10 most frequent A. countries of origin, B. journals of publication, C. interventions assessed, D. devices investigated and E. primary outcomes reported across all airway management studies.

	A. Country	n (%)	B. Journal	n (%)	C. Intervention	n (%)	D. Device	n (%)	E. Primary Outcome	n (%)
1	India	199(13.2%)	*Anaesthesia*	164(10.9%)	Intubation	820(54.5%)	Macintosh	414(27.5%)	Success Rate	413(27.4%)
2	USA	187(12.4%)	*European Journal of Anaesthesiology*	69(4.6%)	SAD	257(17.1%)	Glidescope	172(11.4%)	Procedure time	341(22.7%)
3	Japan	106(7.0%)	*British Journal of Anaesthesia*	64(4.3%)	Drug	99(6.6%)	LMA	152(10.1%)	Oxygenation, ventilation parameters	84(5.6%)
4	Korea	105(7.0%)	*Journal of Clinical Anesthesia*	63(4.2%)	SAD and intubation	71(4.7%)	i-gel	112(7.4%)	Haemodynamic changes	74(4.9%)
5	Germany	89(5.9%)	*Anesthesia and Analgesia*	61(4.1%)	Airway assessment	57(3.8%)	Airtraq	101(6.7%)	Intubation ease/difficulty	69(4.6%)
6	UK	83(5.5%)	*Journal of Anesthesia*	47(3.1%)	FONA	48(3.2%)	Proseal	99(6.6%)	Diagnostic test accuracy	63(4.2%)
7	Turkey	66(4.4%)	*Indian Journal of Anaesthesia*	44(2.9%)	BVM	18(1.2%)	C-MAC	84(5.6%)	Seal/leak pressures	56(3.7%)
8	China	65(4.3%)	*Resuscitation*	41(2.7%)	Pre-oxygenation	15(1.0%)	LMA Supreme	71(4.7%)	Laryngeal view	44(2.9%)
9	Canada	60(4.0%)	*Anesthesiology*	37(2.5%)	Educational	13(0.9%)	ILMA	64(4.3%)	Drug: Intubation conditions	28(1.9%)
10	Iran	46(3.1%)	*American Journal of Emergency Medicine*	36(2.4%)	Cricoid Pressure	9(0.6%)	McGrath	62(4.1%)	Cormack-Lehane Score	24(1.6%)

SAD, supraglottic airway device; FONA, front-of-neck access; BVM, bag, mask ventilation.

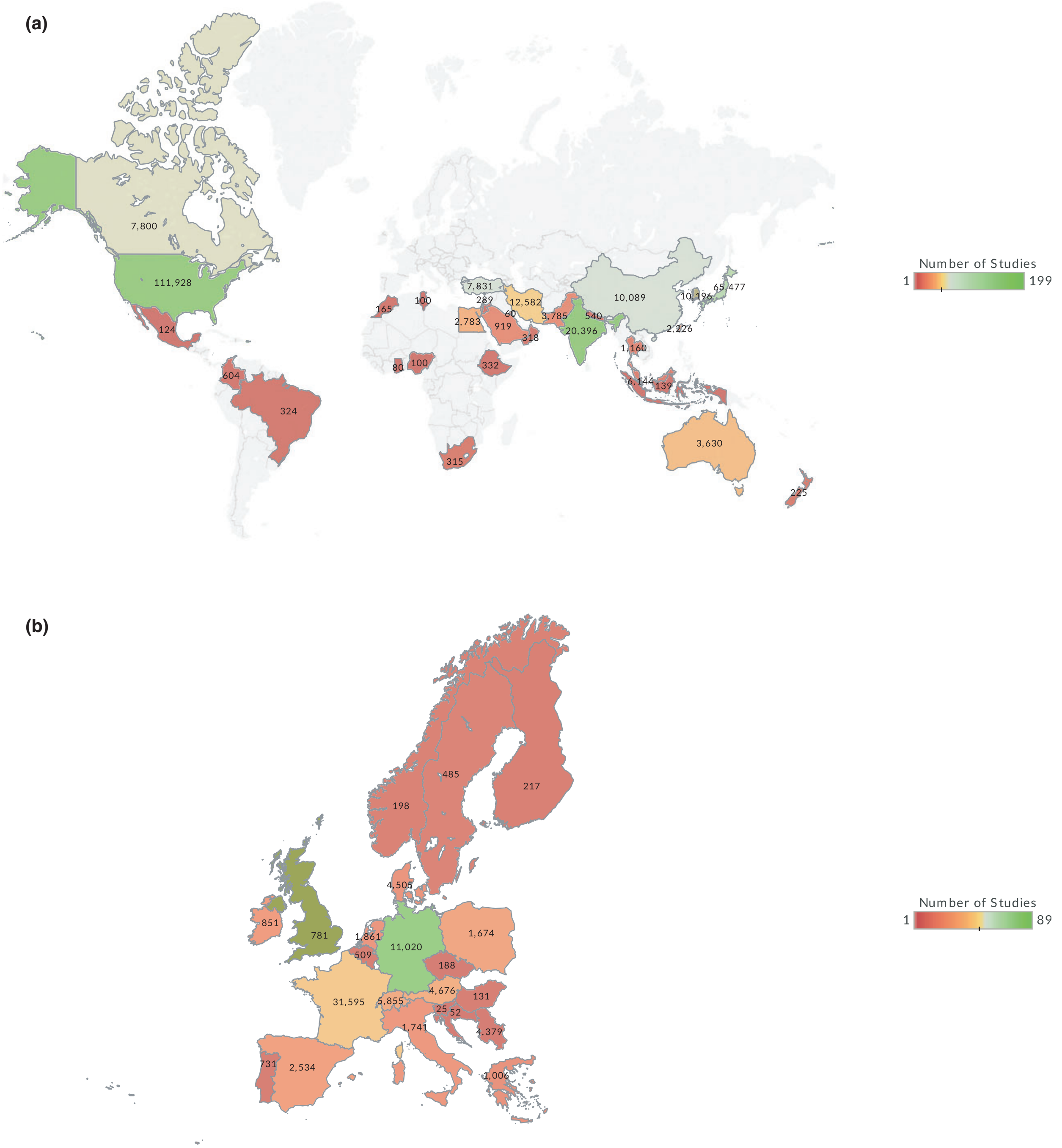

Figure 3 Maps representing the countries from which airway management studies have been published since 2006. (a) All countries excluding Europe. (b) Only European countries. The numbers represent the total number of patients recruited from each country, and the colour indicates the number of publications that have emerged from each country.

This may reflect either an acceptance of the clinical importance of patient studies by investigators or selection bias from journals that have a reduced enthusiasm for manikin studies they had once accepted [20]. Indeed, some may suggest that journals might have already been influenced by the CARE guidelines. Nonetheless, manikins continue to play a significant role in airway management research and training [4, 21, 22], but the benefits and drawbacks of manikin studies on clinical practice remain debated and have been previously described [2, 4, 5, 20].

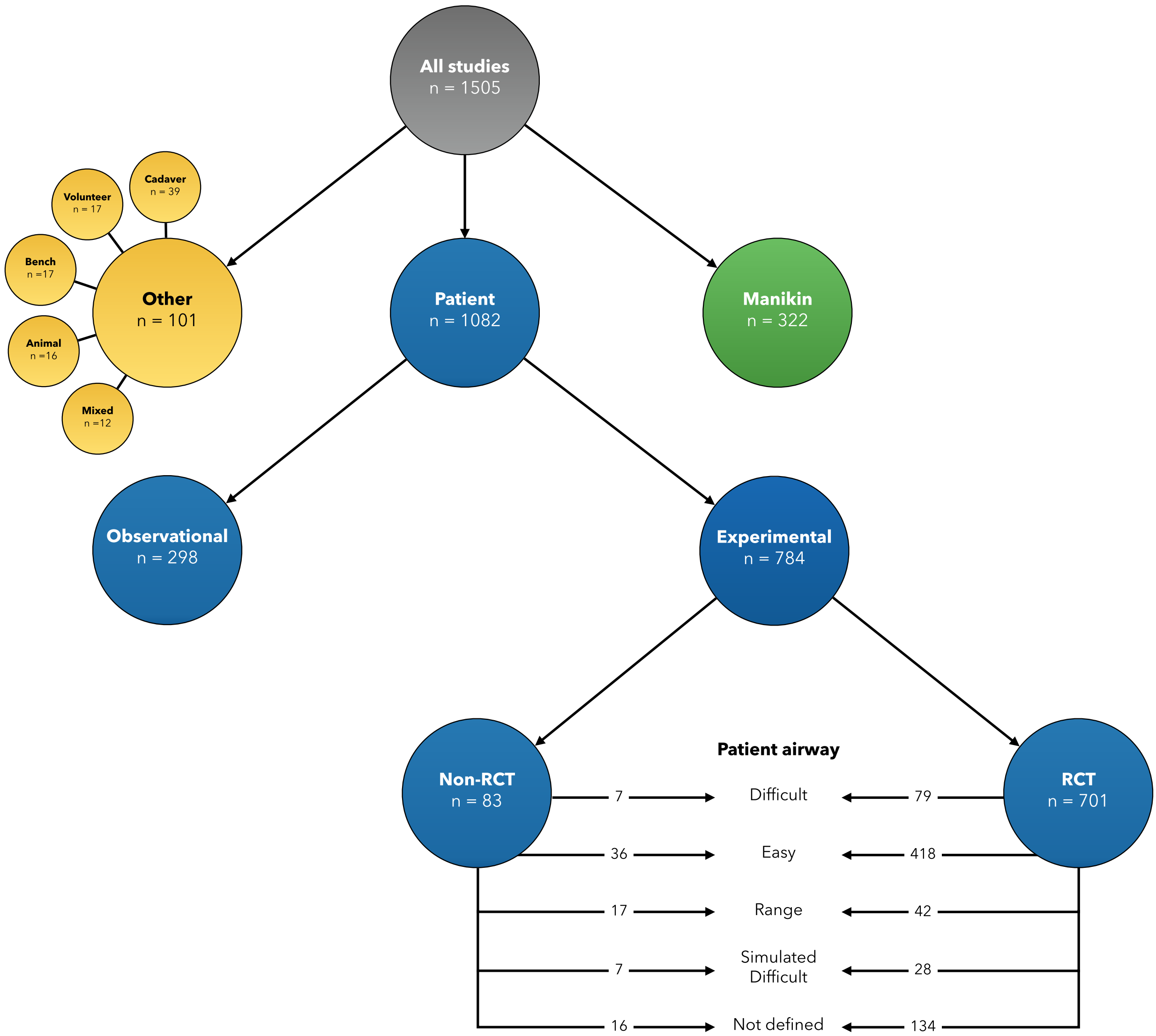

Figure 4 Flow diagram demonstrating study subjects, study design and type of patient airway involved in experimental patient studies. Grey circles are for all studies, blue circles are for patient studies, green circles are for manikin studies and yellow circles are for all other subject types.

Our review found that the largest group of patients studied were those who were not predicted to have a difficult airway. The CARE guidelines advocated that this group should be studied in the main, with difficult airway patients sparingly studied, only with good justification for inclusion in trials. In this regard, the airway literature does seem to be adhering to the guidelines, but this might limit the applicability of many of the results to the difficult airway context.

We found that patient studies on airway management are more likely to involve experienced operators than inexperienced, with the latter more likely to be involved in manikin studies. Again, here the literature seems to be conforming to the CARE guidelines, which recommend that new devices and techniques should only be evaluated by experts.

Our data do not appear to reflect the balance of different airway interventions as are used in clinical practice. For example, the Fourth National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society reported that in more than half of the cases of general anaesthesia, the primary airway management device used was a SAD and 38% involved tracheal intubation [23]. However, tracheal intubation has attracted the most interest among researchers, constituting > 50% of the published prospectively designed studies, followed by 17% for SADs.

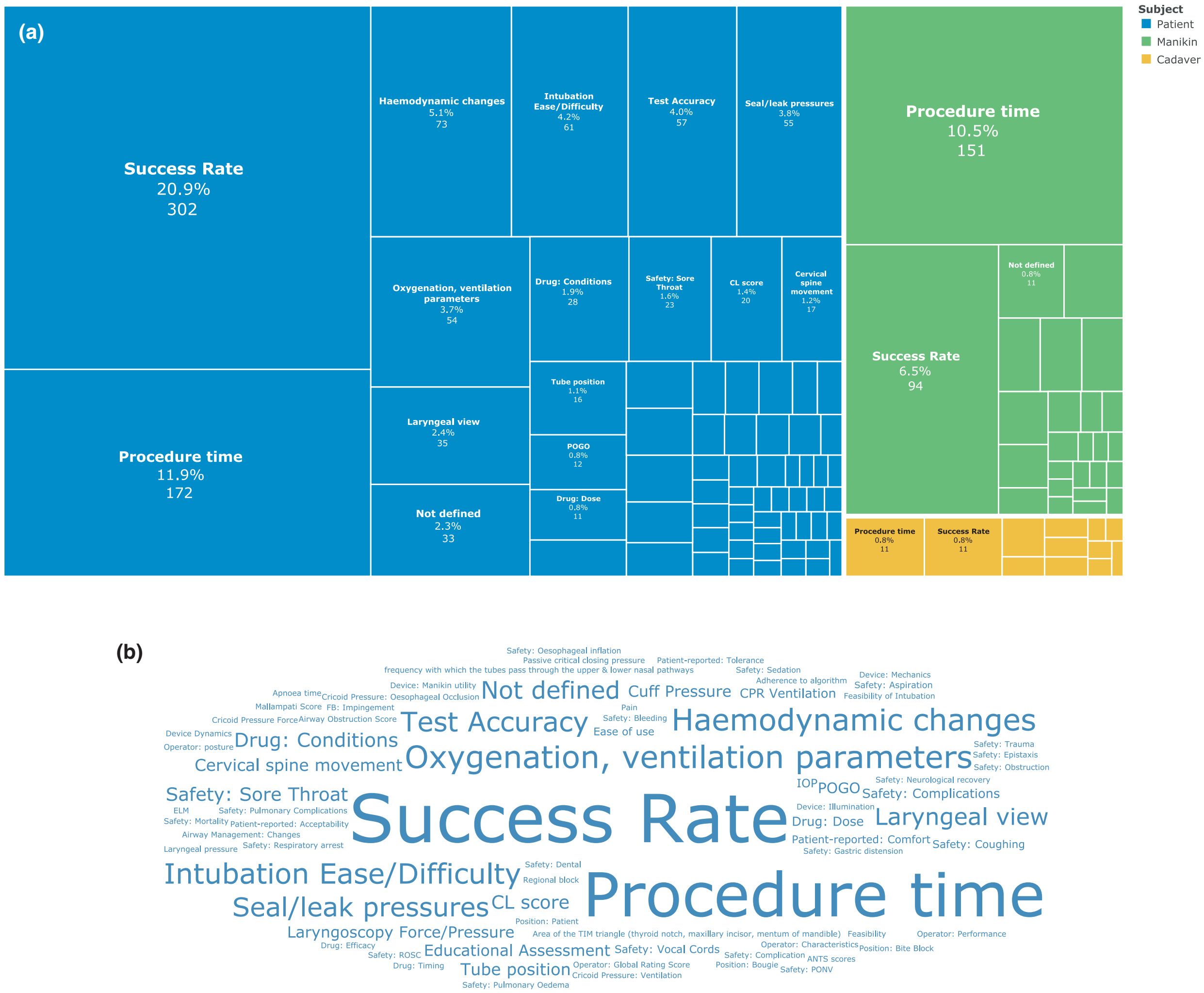

Figure 5 (a) Treemap demonstrating the most commonly used primary outcomes in patient (blue), manikin (green) and cadaver (yellow) studies. The size of each box is proportional to the number of studies reporting each primary outcome. (b) Word cloud of the 66 primary outcomes reported in patient studies. Word size corresponds to the frequency of reporting.

This discrepancy between clinical practice and academic activity extends to other aspects of airway management. Little has been published recently on what may be regarded as the most basic aspects of airway management, such as education, airway assessment, pre-oxygenation and bag-mask ventilation—totalling just 7% of airway management studies. It is possible that these more basic airway interventions have already been investigated before our study period and research is now focusing on the more advanced techniques. However, an alternative and more worrying possibility is that there is passive, yet probably erroneous, acceptance that basic techniques cannot be improved upon. A particular example is that of airway assessment, which only comprises 3.8% of investigated interventions. We are increasingly aware of the limitations of current airway assessment tools as difficulties in tracheal intubation and facemask ventilation continue to be poorly predicted [24–28]. It may be that more investment is required to develop this crucial facet of airway management.

Pedagogical literature was poorly represented, despite a search strategy designed to identify these interventions. Education forms the foundation of clinical decision making, but it appears that researchers focus on the latter rather than the former [29, 30]. Thus, these important, yet understudied, areas may represent important avenues worthy of investigation in future airway management research.

There is a paucity of prospective studies on FONA (3.2%), despite the undoubted importance and recent

Table 2 Clinical safety or complication outcomes in airway management studies. Values are number proportion. Denominator is for patient studies only (n = 1082).

Outcome	n (%)
Sore throat	23 (2.1%)
Complications (range)	8 (0.7%)
Coughing	5 (0.5%)
Aspiration	4 (0.4%)
Vocal cords	4 (0.4%)
Bleeding	3 (0.3%)
Epistaxis	3 (0.3%)
Dental	2 (0.2%)
Mortality	2 (0.2%)
ROSC	2 (0.2%)
Gastric distension	1 (0.1%)
Neurological recovery	1 (0.1%)
Obstruction	1 (0.1%)
PONV	1 (0.1%)
Pulmonary complications	1 (0.1%)
Respiratory arrest	1 (0.1%)
Sedation	1 (0.1%)
Trauma	1 (0.1%)

ROSC, return of spontaneous circulation; PONV, postoperative nausea and vomiting.

controversies [23, 31, 32]. Rather than a perceived lack of importance, FONA research is more likely restricted by the limited number of cases, ethical considerations and feasibility in clinical practice. Indeed, our data report that only 25% of FONA trials have been conducted in patients. There is, therefore, an increasing role for observational studies which we hope will help increase the success and safety of FONA [33, 34]. Our data did not include retrospective study designs, but large database analyses, such as those from the Danish Anaesthesia Database or the Multicenter Peri-operative Outcomes Group in the USA, present invaluable data [35, 36]. These data may have skewed our results due to the large number of patients retrospectively analysed. Regardless, FONA is a procedure where non-patient–based investigations may still be of benefit in the future.

We also found key trends in reported end-points. Time-to-event and success rate were most commonly reported. This is likely a reflection of the feasibility of powering studies to these outcomes, given that the median number of recruited patients was just 87. However, there was a wide range of outcomes reported for similar interventions, with heterogenous definitions. This is common across the medical literature, and the 'core outcomes measures in peri-operative and anaesthetic care–standardised endpoints for peri-operative medicine' (COMPAC-StEP) has been setup to develop a core outcome set for various aspects of peri-operative care [37]. However, this does not extend to airway management interventions. Our data can be used as a framework for this purpose, to ensure clinically important outcomes are appropriately selected, defined and investigated in airway management research [15]. This process should follow recognised guidance on developing core outcome sets [38].

Our results present the most complete picture of airway management research and some of our findings are in contrast with other published work. García-Aroca et al. recently conducted a bibliometric assessment of difficult airway research, and similarly found a year-on-year increase in the number of publications, as well as further support that *Anaesthesia* as a journal is a publishing leader in this field [39]. However, they reported a much lower annual

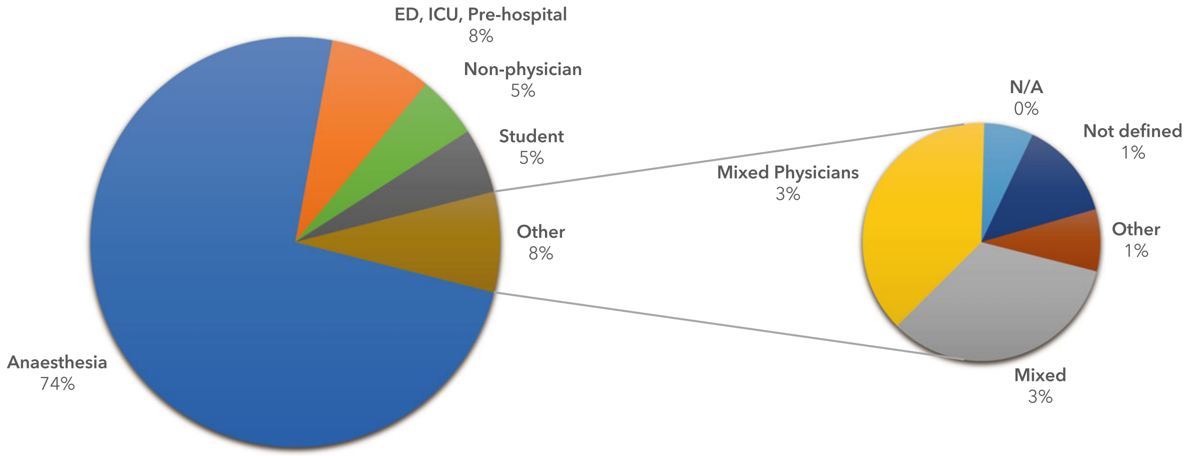

Figure 6 The proportion of studies involving participants from different professional backgrounds.

publication rate than our results revealed, and this was likely due to a much narrower search strategy than we have used in this current study [40].

This study has several limitations. We only included studies published in English, therefore, we have excluded a large proportion of patient studies; for example, we have < 1000 patients recruited from the whole of South America. We excluded paediatric studies, which may have provided further insights into the state of airway management research, particularly in light of recent data demonstrating deficiencies in paediatric and neonatal airway management [41]. By focusing on airway papers published in the past 10 years, we might have missed any publishing trends over a longer time period. A further limitation is that we did not explore the reference lists of studies, which might have led us to miss a small number of studies that would have otherwise been eligible for inclusion. Additionally, we did not assess of the number of authors involved, the number of centres contributing to research and data on funding of airway research [19, 42, 43]. These data would be crucial to further develop airway research strategies but formulating these was beyond the scope of this review. For example, we did not include several key publications that constitute a more 'strategic' approach to thinking about airway management such as the Vortex approach or the 'binary approach' to airway management [44, 45].

In conclusion, we have reported on the state of airway management research between 2006 and 2017. These data can be used to form the basis for future priority setting exercises, core outcome set development, and could inform strategy on the future directions of airway management research.

Acknowledgements

This was prospectively registered with PROSPERO (https://www.crd.york.ac.uk/prospero/ registration ID CRD42017081279). We thank Mr A. Fricker, Head of NHS Partnership and Liaison, Library Services, King's College London, for assistance in conducting the literature search. No external funding was obtained for this study. IA has received honoraria from Ambu, Verathon Medical and Fisher & Paykel for travel and accommodation to attend meetings. KE is on the Editorial Board of *Anaesthesia*.

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Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Appendix S1. Search strategy.

Appendix S2. Studies included in this systematic review.

