





Anesthesiology airway-related medicolegal cases from the Canadian Medical Protection Association

Analyse des dossiers médicolégaux de l'Association canadienne de protection médicale portant sur des problèmes associés aux voies respiratoires en anesthésiologie

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Received: 18 September 2019/Revised: 24 August 2020/Accepted: 25 August 2020/Published online: 16 November 2020 © The Author(s) 2020

Abstract

Purpose We analyzed closed civil legal cases in 2007-2016 from the Canadian Medical Protective Association (CMPA) involving specialist anesthesiologists where airway management was the central concern.

Methods We included all airway-related civil legal cases involving specialist anesthesiologists that closed from 2007 to 2016. The following variables were abstracted by CMPA medical analysts: clinical context, peer expert opinions of contributing factors, and patient and legal outcomes.

Results We found 46 of the 406 (11%) closed cases involving anesthesiologists to be airway-related. Twenty-six cases (57%) involved elective surgery and 31 patients (67%) were categorized as American Society of Anesthesiologists physical status III. Twenty-five cases

This article is accompanied by an editorial. Please see Can J Anesth 2021; this issue.

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Clinical Epidemiology Program, Ottawa Hospital Research Institute, 1053 Carling Avenue, Ottawa K1Y 4E9, ON, Canada (54%) occurred outside the operating room (e.g., postanesthesia care unit, intensive care unit, or other satellite locations). In 19 (42%) cases, there was at least one predictor of a difficult airway. Peer experts identified judgement failures in 30 cases (65%), most commonly inadequate airway evaluation. In 30 cases (65%), the patient died or had a permanent brain injury. The medicolegal outcome favoured the patient in 27 (59%) cases, with a median [interquartile range] payment of 422,845 [257,637-935,673] CAD.

Conclusions Severe patient harm is common when airway management is the focus of a CMPA medicolegal complaint involving anesthesiologists. Patients were otherwise typically low risk cases presenting for elective surgery. Failure to assess or to change management based on the airway exam or encountered difficulty were the most common errors. Our findings support the continued need for adoption, adherence, and practice of guidelines for anticipated and unanticipated difficult airway management for every patient encounter.

Résumé

Objectif Nous avons analysé les dossiers d'actions civiles de l'Association canadienne de protection médicale (ACPM) conclus entre 2007 et 2016 qui impliquaient des anesthésiologistes mettaient principalement en cause la gestion des voies respiratoires.

Méthode Nous avons inclus tous les dossiers d'actions civiles mettant en cause la gestion des voies respiratoires et impliquant des anesthésiologistes, conclus entre 2007 et 2016. Les analystes médicaux de l'ACPM ont examiné les variables suivantes: le contexte clinique, les opinions des experts sur les facteurs contributifs, ainsi que



les issues des actions en justice et les résultats cliniques pour les patients.

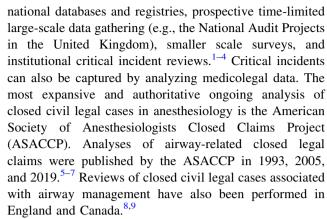
Résultats Parmi les 406 dossiers conclus impliquant des anesthésiologistes, 46 (11%) portaient sur des problèmes liés aux voies respiratoires. Vingt-six de ces dossiers (57%) portaient sur des cas de chirurgie non urgente et 31 patients (67%) étaient considérés comme ayant un état physique relevant de la classification I ou II de l'American Society of Anesthesiologists. Dans vingt-cinq dossiers (54%), les problèmes sont survenus en dehors de la salle d'opération (par ex., salle de réveil, unité de soins intensifs, ou autre emplacement satellite). Dans 19 dossiers (42%), il y avait au moins un prédicteur de difficultés dans la prise en charge des voies respiratoires. Les experts ont relevé des erreurs de jugement dans 30 dossiers (65%), la plupart du temps liées à une évaluation inadéquate des voies respiratoires. Dans 30 dossiers (65%), le patient est décédé ou a subi des lésions cérébrales permanentes. L'issue médicolégale a été favorable au patient dans 27 dossiers (59%), montant médian [écart interquartile] du paiement étant de 422 845 [257 637-935 673] CAD.

Conclusion Il est fréquent que des patients subissent des préjudices graves lorsque la prise en charge des voies respiratoires fait l'objet d'une plainte médicolégale auprès de l'ACPM qui met en cause des anesthésiologistes. Dans les dossiers analysés, les patients étaient généralement considérés à faible risque en vue d'une intervention chirurgicale non urgente. Les erreurs les plus fréquentes étaient une mauvaise évaluation des voies respiratoires ou la non-modification de la prise en charge des voies respiratoires à la suite de l'évaluation ou de difficultés rencontrées. Selon nos conclusions, il est impératif de continuer d'adopter, de respecter et de mettre en pratique les lignes directrices concernant la prise en charge de voies respiratoires difficiles, anticipées ou non, lors de chaque rencontre avec un patient.

Keywords malpractice · anesthesiology · airway

Introduction

The specialty of anesthesiology has a long history of improving patient safety. Much of this progress has been achieved by evaluating patient outcomes to determine risks to safety, and by deploying new strategies to counter these risks. Reviews of critical incidents (including those resulting in unintended harm during care), whether done locally or nationally, have led to the development and adoption of new technologies, protocols, clinical practice guidelines, and cognitive aids intended to improve care. Critical incidents can be identified by such means as



The Canadian Medical Protective Association (CMPA) is a not-for-profit mutual defense organization that represents over 95% of Canadian physicians. The mission of the CMPA is to protect the professional integrity of physicians and promote the safety of medical care in Canada. Unlike other medical malpractice insurance companies in the United States or Europe, the CMPA is not an insurance company. It provides a broad range of services to its members outside of the constraints of an insurance contract, which typically limits the scope of assistance offered to the policyholder and the indemnification that might be paid to the policy limit. The CMPA maintains a national repository of coded medicolegal cases relating to both civil legal actions and complaints to physician regulatory authorities (e.g., provincial Colleges of Physicians and Surgeons or territorial medical regulatory authorities). Ongoing analysis of these cases is integral to the multi-level education services and programs that the CMPA provides to its members.

The last CMPA airway-related anesthesiologist-based closed civil legal case report encompassed 1993-2003. Airway management in anesthesia practice has substantially changed since the last report. In particular, there is evidence that the further development and widespread deployment of new technologies such as video laryngoscopes and flexible bronchoscopes has had a positive impact on outcomes of care. As well, new iterations of guidance documents from specialty societies and interest groups have provided anesthesiologists with updated strategies to assess the patient airway and safely manage both unanticipated and anticipated difficulties. 11,12

Given that the last study of Canadian airway-related anesthesiologist medicolegal cases preceded these advances, and to assess contemporary anesthesia practice, we analyzed the nature of closed airway-related medicolegal cases for the most recent ten-year period for which data were fully available. We conducted a retrospective descriptive analysis of airway-related anesthesiology civil legal cases that were closed in 2007-



2016, looking for potential patterns of healthcare-related patient harm that could inform patient safety initiatives.

Methods

Study design and case selection

This study was a retrospective descriptive analysis of CMPA aggregate data derived from civil legal cases closed from 1 January 2007 to 31 December 2016, and which involved anesthesiologists, where airway management was the central focus of the case. At the CMPA, case closure indicates that a final medicolegal outcome was determined by the court or regulatory authority or by a mutual agreement between the parties to resolve the action. The most recent ten-year period for which data were available was chosen as the authors wanted to focus on contemporary anesthesia practice. These closed cases were in the public domain and are presented here in aggregated data form. The Advarra Institutional Review Board approved the study (Protocol #Pro00020829; most recently approved with amendments # MOD00587430, on 24 February 2020).

The files were searched according to the CMPA type of work, and only files that included anesthesiologists who were Fellows of the Royal College of Physicians of Canada (FRCPC) were included; family physician anesthetists were not included in this review. We identified files that included anesthesiologists who were CMPA members named in civil legal cases involving either the act of securing an airway, and/or a complication arising from airway management (e.g., respiratory distress/failure) in any clinical care location. To avoid misrepresenting the frequency of certain outcomes, class action cases were excluded.

Data repository and medicolegal coding

Canadian Medical Protective Association records are organized by "case", representing instances in which a physician contacted the CMPA regarding a medicolegal matter involving that physician. Medical analysts (registered nurses extensively trained in medicolegal research) review each case and code specific clinical details using the Canadian enhancement to the International Statistical Classification of Diseases and Related Health Problems, 10th revision, Canada and the Canadian Classification of Health Interventions (CCI). Analysts use an in-house CMPA coding framework to categorize patient safety incidents and the contributing factors (categorized as provider-, team-, or system-related)

based on peer expert opinions (see Appendix A for glossary of medicolegal terms). 14

In this context, we defined peer experts as physicians retained by the parties in a legal action to interpret and provide their opinion on clinical, scientific, or technical issues surrounding the care provided. They are typically of similar training and experience as the physicians whose care they are reviewing. Severity of patient harm is determined using a modified version of the American Society for Healthcare Risk Management's Healthcare Associated Preventable Harm Classification. 15 This allows patient harm that is related to healthcare to be identified rather than patient harm from inherent risks of care or near misses, or no harm, as defined in Appendix A. For example, undetected esophageal intubation resulting in patient anoxic brain injury is a healthcare-related harm. In comparison, a case where a patient with end-stage emphysematous bullous disease who, despite being counselled preoperatively by the anesthesiologist on the risks of positive-pressure ventilation, nonetheless has a pneumothorax while undergoing appendectomy, would be an example of the inherent risk of care.

Data collection

Variables abstracted from the cases included patient characteristics such as age and American Society of Anesthesiologists (ASA) physical status. Details of patient care were also abstracted including type of airway management, and location and urgency of patient care. Location of care was divided into hospital versus nonhospital (e.g., freestanding clinic) locations. Hospital location was further divided into operative areas (preoperative, intraoperative, and postoperative locations) and non-operative areas (e.g., emergency department, critical care areas). In addition, the perioperative phase of care (i.e., pre-, intra-, or postoperative) when patient harm occurred was abstracted. Analysts also abstracted predictors of difficult airway management and degree of patient harm. The analysts sought out themes in peer expert criticisms and recorded the medicolegal outcome including any costs arising from court awards or settlements.

Statistical analysis

We report all variables with frequencies and proportions and calculated medians [interquartile range (IQR)] using SAS software, version 9.4 for all statistical analyses (SAS® Enterprise Guide® software, Version 9.4. Cary, NC, USA: SAS Institute Inc.; 2013).



Results

In the period from 2007 to 2016, the CMPA closed 406 legal cases involving FRCPC anesthesiologists. Of these, 46 (11%) cases involving 47 patients identified complications related to airway management (one case involved two patients). Anesthesiologists were identified as the only specialty involved in 30 (65%) cases. Residents or other trainees were involved in three cases.

Patient characteristics

The patient characteristics and clinical circumstances are detailed in Table 1. Twenty-six (57%) involved elective surgery. In 16 of 26 (62%) of these elective cases, patients either sustained brain injury or died. In 13 (50%) of these elective cases, patients were classified as ASA physical

status I-II, 8 (31%) as ASA physical status > II, and five (19%) had no ASA assigned. Table 2 identifies the predictors of difficult airway as determined by CMPA analyst manual review of the health records. In 27 (59%) cases, no predictors were identified and/or no airway evaluation was documented.

Location of care and airway management events

Of the 46 cases, 41 (89%) had care provided in a hospital setting and five (11%) in an out-of-hospital setting. In 35 of the 41 (85%) hospital-setting cases, care was provided in an operative area. Specific airway management events (one component of care provided) took place in operative settings in 27 cases, critical care locations in eight cases, and non-critical care hospital locations in three cases. Some cases included more than one airway management

Table 1 Patient and case characteristics for CMPA closed cases, 2007-2016 (n=46 cases)

	n (%)
Patient demographics ($n = 47$ patients/46 cases)	
Male	26 (55)
ASA physical status I–II*	23 (67)
ASA physical status III–V	15 (32)
Emergency indication	10 (22)
Pediatric	9 (19)
Age, yr (mean, standard deviation)	42 (22)
Age > 65 yr	5 (11)
Obese	18 (38)
Primary anesthetic (anesthetic type initially provided to patient)	
General	34 (74)
Regional	2 (4)
Monitored anesthesia care	3 (7)
None (non-surgical cases)	7 (15)
Procedures	
Head and neck	8 (17)
Cervical spine	2 (4)
Non-surgical intubation or airway management	5 (11)
Obstetric	3 (7)
Chest/abdomen	20 (43)
Orthopedic	5 (11)
Lumbar spine	3 (7)
Location of airway event	
Operating room	21 (46)
Post-anesthesia care unit	6 (13)
Intensive care unit	6 (13)
Ward or floor	2 (4)
Emergency department	2 (4)
Other or unspecified	9 (20)

^{*}Not all patients had an ASA physical status assigned. ASA = American Society of Anesthesiologists; CMPA = Canadian Medical Protective Association.



Table 2 Difficult airway predictors identified in CMPA closed cases, 2007-2016 (n = 46 cases)

	N (%)
Indicators of a difficult airway (whether known/recognized at the time or not) or factors that contributed to difficult airway management	
Airway obstruction from any cause (e.g., sleep apnea/acute pathology)	12 (26)
History of difficult intubation	1 (2)
Mallampati grade 3–4	2 (4)
Limited cervical spine extension	3 (7)
Limited mouth opening	4 (9)
Secretions/blood in airway	1 (2)
Short neck	3 (7)
Swollen tongue	1 (2)
Thick or bull neck	1 (2)
Pre-eclampsia	1 (2)
Number of predictors	
1	13 (28)
2–6	6 (13)

CMPA = Canadian Medical Protective Association.

event. Three of five out-of-hospital cases with airway management events occurred in an out-of-hospital clinical setting. Not all locations were clearly specified in the medicolegal record. The urgency of the airway event is reported, stratified by location, in Table 3.

Patient safety incidents

Analysts reviewing the files concluded that 33 of the 46 (72%) patient safety incidents resulted from the provision of healthcare, 12 (26%) were inherent risks of the care provided, and one patient outcome was unrelated to the healthcare experience and was a result of natural disease progression (Fig. 1).

Peer expert criticisms of care provided

There were 260 peer experts who reviewed the 46 cases and offered assessments of the care provided. Peer experts were critical of some aspects of the care in the majority of cases (39/46, 85%); these included inappropriate management decisions and clinical judgement failure. Specific criticisms are detailed in Table 4. The most common deficit in clinical care cited by the peer experts was inadequate preoperative patient evaluation, including information gathering and failure to record an airway evaluation in 27 (59%) of the claims. Deviations from Canadian Anesthesiologists' Society standards of care at the time that care was delivered (e.g., not using standard

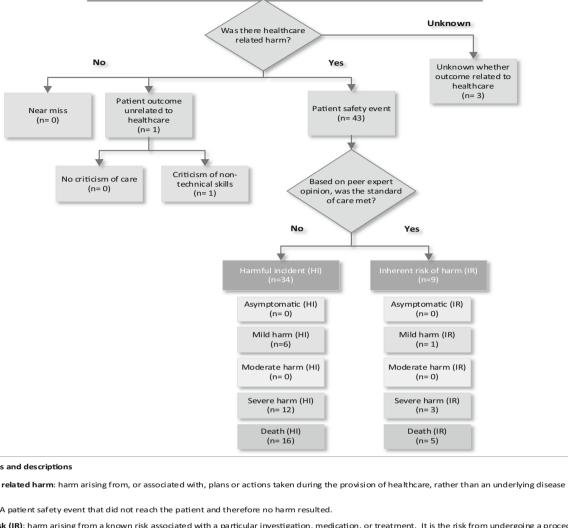
Table 3 Urgency of airway by location for CMPA closed cases, 2007-2016 (n = 46 cases)

Location	Elective <i>n</i> (% of 26)	Urgent n (% of 10)	Emergency <i>n</i> (% of 10)
Operating or procedure room	16 (62)	2 (20)	3 (30)
Postanesthetic care unit	1 (4)	3 (30)	2 (20)
Intensive care unit	2 (8)	3 (30)	1 (10)
Emergency department	1 (4)	1 (10)	0 (0)
Other**	6 (23)	1 (10)	4 (40)
Labour and delivery room	2 (8)		
Diagnostic imaging unit	1 (4)		
Doctors office*	2 (8)		
Surgical clinic*	1 (4)		

^{*}Out-of-hospital locations.



^{**}Not all locations were available for airway management events. CMPA = Canadian Medical Protective Association.



CMPA terms and descriptions

Healthcare related harm: harm arising from, or associated with, plans or actions taken during the provision of healthcare, rather than an underlying disease or

Near miss: A patient safety event that did not reach the patient and therefore no harm resulted.

Inherent risk (IR): harm arising from a known risk associated with a particular investigation, medication, or treatment. It is the risk from undergoing a procedure in ideal conditions, performed by qualified staff using current research, equipment and techniques – based on peer expert opinion.

Harmful incident (HI): harm results from the care or services provided to the patient due to failures in the processes of care or in the performance of procedures,

Death: Healthcare-related death.

Severe: Patient harm is symptomatic, requiring life-saving intervention or major medical/surgical intervention, or resulting in a shortening life expectancy, or causing major permanent or temporary harm or loss of function.

Moderate: Patient harm is symptomatic, requiring intervention (e.g. additional operative procedure, additional therapeutic treatment), and increased length of stay, or causing permanent or temporary harm, or loss of function.

Mild: Patient harm is symptomatic, symptoms are mild, loss of function or harm is minimal (permanent or temporary), and minimal or no intervention is required (e.g. extra observation, investigation, review, or minor treatment).

Asymptomatic: A patient safety event or patient safety incident that reached the patient but the patient reports no symptoms and no treatment is required.

Fig. 1 Patient harm flowchart

equipment such as pulse oximetry) were present in ten (22%) of the cases. These deficits were deemed by the peer experts to have negatively impacted the anesthesiologist's ability to diagnose and develop alternative plans when difficulties with airway management were encountered. Communication issues were also identified by peer experts as contributing to poor patient outcomes and involved failed interactions between the principal care provider and other members of the team, as well as between trainees and supervising physicians (five cases) (Fig. 2).

Concerns identified by peer experts arose during various phases of anesthesia care. Care during the pre-induction phase was most frequently criticised, with inadequate preoperative evaluation of risk factors such as difficult airway history or comorbid conditions (e.g., sleep apnea, obesity) and/or inadequate airway examination or

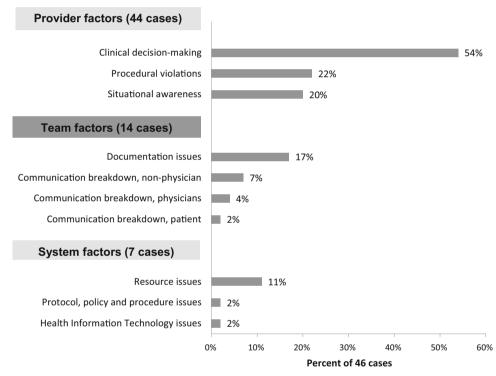


Table 4 Peer expert and analyst-identified judgement failures for CMPA closed cases, 2007–2016 (n = 46 cases)

	N (%)
Inappropriate difficult airway management	
Failure to use supraglottic airway as a bridge	1 (2)
Perseveration	5 (11)
Failure to plan for difficult airway management (induction)	7 (15)
Delay in calling for, or failure to call for, a surgical airway	2 (4)
Inadequate preoperative or airway evaluation	27 (59)
Number of judgement failures	
None of the above (appropriate management)	16 (35)
1	20 (43)
2–5	10 (22)

CMPA = Canadian Medical Protective Association.

Fig. 2 Factors contributing to the 46 medicolegal cases involving airway management



Note: Cases may involve more than one contributing factor

documentation identified in 27 cases (59%). A complete lack of a documented preoperative airway examination was identified in ten (26%) of the operative cases.

In the induction, maintenance, and extubation phases, we identified peer expert criticisms in 20 of 39 cases (51%), whereas the standard of care was met in the remaining seven cases. Specific issues cited by peer experts during the induction and maintenance phases included failure to recognize esophageal intubation (three cases), failure to ensure endotracheal tube patency, failure to manage a deteriorating or difficult-to-ventilate patient, and not meeting the current Canadian Anesthesiologists'

Society standards for monitoring (e.g., oxygen saturation or carbon dioxide monitoring). Other concerns cited by peer experts included the anesthesiologist setting alarms to a low (or silent) mode and failure to use neuromuscular monitoring to verify the adequacy of recovery and/or reversal of muscle relaxants.

In the post-extubation phase of care, peer experts identified concerns in 11 of 39 (28%) cases, which occurred in a variety of care locations. Specific concerns included lack of pulse oximetry monitoring, failure to consider the impact of opioids on the potential for respiratory insufficiency/arrest, and a lack of



Table 5 Patient outcomes and payment amounts for CMPA closed cases, 2007-2016 (n = 46 cases)

	N (%)	
Death or permanent brain damage	30 (65)	
Airway injury	3 (7)	
Paid on behalf of anesthesiologist	27 (59)	
Anesthesiologist payment amounts (CAD)		
Median	422,845	
Interquartile range	257,637–935,673	

CMPA = Canadian Medical Protective Association.

documentation of specific patient monitoring or follow-up communication to guide subsequent care.

In both in-hospital (but non-operative) and out-of-hospital cases, peer expert concerns were related primarily to clinical decision-making, such as failure to use pulse oximetry or waveform capnography to confirm endotracheal tube placement as well as failure to diagnose issues with endotracheal tube placement and/or patency in patients who became difficult to ventilate/oxygenate.

Finally, in the three cases involving residents, peer experts criticised the lack of supervision by staff physicians, residents failing to anticipate problems, deficient skill sets for managing higher acuity patients, delays in recognizing a deteriorating clinical situation, and delays in communicating with staff physicians when difficulties were encountered.

Patient harm

Of the 46 patients, seven (15%) had mild harm (e.g., deficits in concentration), 14 (30%) had moderate to severe harm (of which 11 [24%] had anoxic brain damage—five [45%] elective cases, four [36%] urgent, and two [18%] unknown), and 24 (52%) died (19 [79%] deaths were related to airway management—11 [58%] elective cases, three [16%] urgent, and five [26%] emergent) (Table 5). In one instance, the patient outcome was considered to be unrelated to the healthcare provided and is not included here.

Medicolegal outcomes

The medicolegal outcome was favourable for the plaintiff (see Appendix A for glossary) in 27 (59%) cases with settlement in 26 of these and a judgement for the plaintiff in one. Eighteen (39%) cases were dismissed, and one (2%) judgement was for the anesthesiologist (Table 5). Two of the six remote (from the operative setting) cases had medicolegal outcomes that were favourable for the plaintiff. In four of five cases that involved an out-of-

hospital setting, the anesthesiologist was assigned sole responsibility for the care and all four cases had an unfavourable outcome for the anesthesiologist.

Discussion

Patient care issues that were identified by peer expert reviewers in this series of closed civil legal cases can be categorized according to the phase of anesthesia care: preoperative assessment, induction and initial airway management, maintenance of anesthesia, postoperative care. Inadequate or undocumented preoperative airway assessment occurred in the majority (59%) of cases. Although the utility of the preoperative airway exam in predicting difficulties with airway management has been scrutinized and found wanting, its most important role may be as a "cognitive-forcing" strategy to encourage the creation of an airway strategy for every patient. 16-18 Although 59% of patients in this series did not have any documented predictors of anatomic airway difficulty, in many cases where airway assessment was documented, it was found to be lacking or incomplete; 41% of patients had predictors of potential airway difficulty. Lack of difficult airway anticipation and failure to consider the implications of identifiable risk factors for difficulty were common themes noted and criticized by peer experts reviewing the care provided.

Peer experts were also critical of specific decisions taken once difficulties were encountered with airway management. Perseveration with techniques that were failing to achieve the intended outcome, rather than pursuing alternate strategies, was identified in five cases (11%). Perseveration was also identified as an important factor leading to adverse patient outcomes in a quarter of the cases contained in the most recent report of the ASA Closed Claims Project (ASACCP) on the management of difficult tracheal intubation. Perseveration was defined by these authors as the consistent application of any airway management technique or tool for ≥ three attempts without



deviation or change of technique, or the return to a technique or tool that had previously been unsuccessful. Perseveration is a judgement error related to loss of situational awareness in the potential setting of lack of alternative equipment or the skills to use alternative equipment. We cannot be certain in our series as to which of these, if any, explained the behaviours criticized by the peer experts. Failure to use a supraglottic device as a bridge for oxygenation was also cited by experts as inappropriate in one case in our series, and again was identified as the most common judgement failure in the recent report from the ASACCP (occurring in 26% of difficult airway claims). Finally, a reluctance to move to an emergency surgical airway when other strategies had failed occurred in two of our series' cases. This is again consistent with the finding in the recent ASACCP report that, even when a decision to move to surgical airway was made, it was delayed 40% of the time. A similar delay to move to a surgical airway in the event of a cannot intubate. cannot oxygenate scenario was also noted in the report of the Fourth National Audit Project (NAP4) of the Royal College of Anaesthetists on major complications of airway management in the United Kingdom.²

The majority of the operative patients were ASA physical status I-II presenting for elective surgery. Peer expert review found that a delay or failure to recognize a deteriorating clinical situation and/or failure to initiate effective interventions in a timely fashion were common. Once a difficulty was encountered, perseveration with failing techniques without modification and non-use of recommended monitoring equipment was also common. Extubation is often difficult during anesthesia care. Poor anticipation of difficulties in the post-extubation phase of care, with no preparations in place to monitor the patient for deterioration or to manage difficulties, was identified in 11 of our reported cases.

A previous CMPA report published in 2005 analyzed airway-related closed civil legal cases between 1993 and 2003. Sixteen airway-related civil legal cases against anesthesiologists were found. These cases involved largely younger patients undergoing elective surgery: 13 (81%) of these patients suffered moderate to severe brain damage or death and case outcomes were commonly unfavourable to anesthesiologists. In this update, which includes 46 cases from 2007 to 2016, more than half (57%) of the cases involved elective surgeries, two-thirds of the operative patients were ASA physical status I-II patients. Moderate to severe injuries or death occurred in 82% of cases, and medicolegal outcome was unfavourable anesthesiologist in 59% of cases.

Analysis of closed civil legal cases across a number of domains, as well as large-scale incident reports such as the NAP4 project in the United Kingdom, show findings consistent with those noted in these reviews of closed CMPA civil legal cases.^{2,5–8} Poor patient outcomes are often related to failure to perform or document a preoperative airway evaluation and the failure to plan for failure. The clinical setting for many of these cases was a reasonably straight-forward elective clinical scenario rather than an extreme patient circumstance in which the applied technologies or guidance strategies failed.

We do not know how often some of the practice issues identified by the peer experts in this series occur during the daily provision of anesthesia care, but they might not be as uncommon as we would like to think. For example, failure to either conduct a preoperative airway assessment or to modify the management plan accordingly is a pattern of practice identified in multiple analyses of closed civil legal cases as well as in audits of practice.2,5-8 It is also inconsistent with recommendations offered by any and all authorities providing guidance for airway management in anesthesia practice. The phrase "normalization of deviance" was coined by Diane Vaughan to describe behaviours that deviate from safe practice but which may be supported by some rationale and may be commonly encountered. 19-21 The behaviours might be justified as necessary in that they allow for the timely completion of tasks, such as moving the operative schedule along more efficiently by not pausing to prepare for plausible but low probability difficulties. The result is that safety boundaries may cease to be consciously recognized over time and, if negative consequences to these violations have not yet been experienced by the individual practitioner, practices may actually be deemed to be safe. The lack of bad outcomes can reinforce practices, because past "successes" negate the objective assessment of risk and what began as a deviation from safe practice eventually becomes "normalized" practice. If and when a poor outcome occurs, it may be regarded as the inevitable consequence of care rather than the result of risk-enhancing behaviours.²² Many of the behaviours identified in this review could be described by this construct and it may be that they persist in practice because practitioners typically get away with them. For example, it is acknowledged that, in many instances, airways that are deemed to be possibly difficult to manage after an assessment is done can turn out to be relatively easily dealt with. Thus, ignoring the results of a concerning assessment may have no consequences for a consecutive series of patients and may lead an anesthesiologist to conclude that doing so is a safe practice—until that strategy fails. It is possible to perform a surprisingly large number of interventions before a plausible adverse event occurs.²³

Many of the errors identified by peer review in this analysis would also be classified as errors of situational awareness. Situational awareness in acute care medicine



has been described as the ability to accurately perceive relevant information in a dynamic environment, comprehend its meaning, and create appropriate strategies to care for the patient.²⁴ Conversely, situational awareness error has been defined as the failure to perceive relevant clinical information, failure to comprehend the meaning of available information, or failure to project, anticipate, or plan. Situational awareness errors are commonly identified in the analysis of adverse outcomes arising from airway management in both closed claims and audits. When the ASA Anesthesia Closed Claims Project database was analyzed to determine the prevalence of situational awareness errors in claims involving death and brain damage, airway and respiratory events were the most common category of clinical events associated with such errors.²⁵ In multiple cases when difficult intubation or inadequate oxygenation or ventilation occurred, the anesthesiologists, while recognizing the difficulty encountered, did not adequately comprehend seriousness of the clinical situation or recognize the deterioration of the patient's condition.

There are important limitations to this review and analysis of closed civil legal cases assessing healthcarerelated patient harm. Patients' motivations for filing complaints or legal claims are complex, although some combination of poor outcome and dissatisfaction with care tends to predominate. It is unknown how many patients are harmed by the provision of healthcare; therefore, closed claims cannot be assumed to be an accurate sampling of healthcare-related patient harm, and there are no denominator data available to assess representativeness. There is typically a considerable time delay between an event happening and the case being filed and closed. Therefore, practices being assessed in closed civil legal cases may be historical in nature; experts might be challenged to appropriately assess care from the past, and current practice expectations may be imposed on temporally distant cases.²⁶ There were 260 peer experts involved in these medicolegal cases and there may have been inter-expert variability in opinions that we did not measure or quantify because not all cases were reviewed by multiple experts. The high severity of injury common in many claims also leads to harsher expert reviews, but severity of injury is not necessarily correlated to the provision of substandard care.²⁷ This hindsight bias may also be encountered in the peer expert case reviews, as more information may become available after the fact that may have influenced care decisions had it been available at the time of the patient encounter.²⁶ There is evidence, however, that in the majority of instances where patients are compensated, both healthcare-related harm and negligent care were present.²⁸ Finally, the documentation reviewed for this study was not collected for research purposes and as such was not always complete, which limited the ability to report on certain specific findings.

Two main conclusions may be drawn regarding this analysis of closed civil legal cases focused on the consequences of airway management in Canadian anesthesiology practice. First, healthcare-related patient harm often arose as a result of failure to manage relatively straight-forward clinical circumstances. Proceeding with care without adequately assessing the patients (including an airway exam), particularly in the setting of otherwise healthy patients presenting for elective surgery, was a common theme. Once airway management difficulties were encountered and the clinical situation began to deteriorate, there was a failure to either recognize or intervene early with an effective salvage strategy. This often resulted in considerable patient harm. Canadian guidance statements directed to the appropriate management of such events are published and their consistent implementation even in the face of well patients presenting for elective surgery is encouraged. 11,12

Author contributions Edward Crosby and Laura Duggan, and Lisa Calder interpreted the results, drafted the manuscript, and reviewed the manuscript. Lisa Calder and Patricia J. Finestone designed the study methods, analyzed the data, and reviewed the manuscript. Richard Liu analyzed the data and reviewed the manuscript. Ria De Gorter interpreted the results and reviewed the manuscript.

Disclosures None.

Funding statement Drs Crosby and Duggan received no funding for this study. All other authors were employees of The Canadian Medical Protective Association.

Editorial responsibility This submission was handled by Dr. Hilary P. Grocott, Editor-in-Chief, *Canadian Journal of Anesthesia*.



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Appendix A Glossary of medical legal terms

Term	Definition		Asymptomatic: A patient safety event or patient safety incident that reached the patient but the
of the negligence or wrongful conduct of the defendant. Several different defendants, such as individual health professionals, hospitals/ institutions, equipment manufacturers, and pharmaceutical companies may be named in a civil legal action. In civil legal actions, these issues are decided on the balance of probability (defendant in a civil action may be found liable if the essential elements of the claim are established on a balance of probability). The "cause of action" or central focus is usually an allegation of negligence, including substandard care and a lack of informed consent. Other allegations in civil legal actions include assault and battery, breach of contract, and breach of fiduciary duty. In civil legal actions, the plaintiff can be awarded monetary compensation as a result of either a successful legal action against the defendant physician(s) or as a negotiated settlement of the claim.			patient reports no symptoms and no treatment is required.
	(damages) for harm or injury suffered as a result of the negligence or wrongful conduct of the defendant. Several different defendants, such as individual health professionals, hospitals/institutions, equipment manufacturers, and	Inherent risk	Based on peer expert opinion, a harmful incident that is a known risk associated with a particular investigation, medication, or treatment. It is the risk from undergoing a procedure in ideal conditions, performed by qualified staff using current research equipment and techniques.
	Patient safety Incident	An event or circumstance which could have resulted, or did result, in unnecessary harm to the patient.	
	established on a balance of probability). The "cause of action" or central focus is usually an allegation of negligence, including substandard care and a lack of informed consent. Other allegations in civil legal actions include assault and battery, breach of contract, and breach of fiduciary duty. In civil legal actions, the plaintiff can be awarded monetary compensation as a result of either a successful legal action against the defendant physician(s) or as a negotiated		<i>Harmful incident</i> : A patient safety incident that resulted in harm to the patient.
			No harm incident : A patient safety incident that reached the patient but no discernible harm resulted.
			Near miss : A patient safety incident that did not reach the patient.
		Peer expert	Physicians retained by parties in the legal actions who interpreted and provided their opinions on clinical, scientific, or technical issues surrounding the healthcare provided and the alleged injuries sustained; typically, of similar training and experience as the physicians whose care they were reviewing.
		Settlement	An agreement, usually monetary, made between opposing parties in a lawsuit to resolve the legal

Appendix continued

Term

Harm

Definition

function.

Death: Healthcare-related death

life-saving intervention or major

Severe: Patient harm is symptomatic, requiring

medical/surgical intervention, or resulting in a

permanent or temporary harm or loss of function.

intervention (e.g., additional moderate or minor

shortening life expectancy, or causing major

Moderate: Patient harm is symptomatic, requiring

operative procedure, additional therapeutic

treatment), or an increased length of stay, or causing permanent or temporary harm, or loss of

Mild: Patient harm is symptomatic, symptoms are mild, loss of function or harm is minimal

(permanent or temporary), and minimal or no intervention is required (e.g., extra observation, investigation, review, or minor treatment).

dispute. A lawsuit can be settled at any stage

before the trial is concluded.



Appendix B Inclusion codes

Inclusion codes based on the *Canadian Classification of Health Interventions* 2018 (CCI) used to identify airway interventions in the CMPA data and *International Statistical Classification of Diseases and Related Health Problems*, tenth revision, Canada, 2018 (ICD-10-CA) to identify airway complications that were associated with an anesthesiologist.

Description	Section and group (CCI field 1 and 2)
Therapeutic	1.GJ.50.^^- Dilation, trachea
interventions	1.GJ.54.^^- Management of internal device, trachea
	1.GJ.55.^^- Removal of device, trachea *****(exclude 1.GJ.55.BA-EB,1.GJ.55.CA- EB,1.GJ.55.JA-EB,1.GJ.55.LA-EB)
	1.GZ.31.^^- Ventilation, respiratory system NEC
	1.GZ.38.JA-ND- Management of positive pressure ventilator
	1.GZ.38.JA-NE- Management of positive pressure end expiratory pressure ventilator (PEEP)
	1.FA.53.^^- Implantation of internal device, nasopharynx
	1.FA.55.CA-NB- Removal of airway [nasopharyngeal] using per orifice approach
	1.GJ.77.^^- Bypass with exteriorization, trachea
	1.NA.53.CA-NB- implantation of airway [esophageal obturator] using per orifice approach
Complication	J95.8- Other post procedural respiratory disorders
codes	J96.0- Acute respiratory failure
	J96.9- Respiratory failure, unspecified
	R09.2- Respiratory arrest
	Y65.3 Endotracheal tube wrongly placed during anesthetic procedure

CMPA contributing factor terminology

Contributing factor	Description	
Clinical evaluation and	Deficient histories and general evaluation.	
decision-making	Issue involving a provider's decision- making related to the selection and management of patient care.	
Deficient knowledge, skills, or technique	Issue involving a provider's clinical knowledge, skill, technique, training, or education.	
Procedural violations	Issue or violation involving:	
	 Administrative policies and procedures of a physician's office, clinic, institution, or regional health authority that are designed to prevent or mitigate error. 	
	 Clinical practice guidelines specified by a regulatory authority (college or government) or specialty. 	
	 Common clinical tasks as per a standard checklist, protocol, care map, clinical pathway, and decision tree; specified by institution, department, or care team. 	
	 Wrong application or improper use of healthcare equipment. 	
Misidentification of anatomy	Intervention inadvertently performed on incorrect anatomical structure or organ. Includes mistaking one structure for another.	
Delayed recognition of injury	Misdiagnosis, missed diagnosis, or delay in diagnosis.	
Informed consent	Issue involving the discussion or documentation of the risks, limitations, side effects or alternative options of a diagnostic test or therapeutic intervention (e.g., pharmacotherapy, surgery).	
Documentation	Inadequate documentation or delay or failure to complete documentation (written or electronic). Including ambiguous, deficient, or illegible medical records.	
Equipment or resource issue	Faulty or malfunctioning healthcare equipment.	
	Insufficient or unavailable healthcare resources; including beds, staff, equipment.	
System administrative protocols	Issue involving an institutions administrative policies and procedures designed to prevent or mitigate error.	

CMPA = Canadian Medical Protective Association.



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