

BMJ Open Multicentre international observational study on airway management for anaesthesia: the STARGATE study protocol

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ABSTRACT

Introduction More than 300 million major surgical procedures are carried out under general anaesthesia each year worldwide, and advanced airway management remains one of the leading daily challenges for clinicians. Data from large international prospective cohort studies on adverse events such as cardiovascular collapse, cardiac arrest and severe hypoxaemia during advanced airway management to facilitate anaesthesia are lacking.

Methods and analysis The International obSservational sTudy on AiRway manaGement in operAting room and non-operaTing room anaEsthesia (STARGATE) study will be an international prospective observational cohort study describing the incidence of major adverse events associated with advanced airway management (tracheal intubation or supraglottic airway device placement) for general anaesthesia in the operating and non-operating room for surgery and medical procedures. The secondary aim will be to describe the practice of airway management in a large international cohort. Critically ill patients will be excluded from this study. Data on patients' characteristics, type of procedure and the adopted airway management strategy, post-procedure adverse events, operator characteristics and in-hospital mortality will be prospectively collected. The study aims to enrol 10 500 patients.

Ethics and dissemination The study has been approved by the Ethics Committee of the coordinating centre (Comitato Etico Interaziendale AOU San Luigi Gonzaga, N° 25/2023). Each of the participating centres will then seek approval of their local Ethics Committee before enrolment. Data will be disseminated to the scientific community by original articles submitted to international peer-reviewed journals.

Trial registration number [NCT05759299](https://clinicaltrials.gov/ct2/show/study/NCT05759299).

INTRODUCTION

According to the WHO, more than 300 million major surgical procedures are

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This is a large, prospective, international, multi-centre, cohort study designed to capture real-world practices in advanced airway management under anaesthesia.
- ⇒ Inclusion of centres from a wide range of healthcare settings, including low- and middle-income countries, will improve the generalisability of findings.
- ⇒ Use of a standardised case report form and pre-specified variable definitions will enhance data consistency and minimise information bias.
- ⇒ The observational design precludes causal inference and may be subject to residual confounding.

carried out under general anaesthesia each year worldwide.¹ Despite important technological advances, airway management remains a major challenge in anaesthesiology.² The Fourth National Audit Project of the Royal College of Anaesthetists, published in 2011, for the first time addressed the need to systematically collect information on major airway-related complications in both the anaesthesia and critical care settings. While the report provided important insights for improvement in the critical care setting, the incidence of major adverse events such as death, brain damage and need for emergency surgical airway appeared underestimated in anaesthesia.^{3,4}

Traditionally, airway management in anaesthesia has been described as *anatomically difficult* as distinct from airway management in critical care which may be both anatomically and *physiologically difficult*.⁵ Indeed, the majority of patients undergoing elective

surgery normally has adequate physiological reserve to cope with perioperative stress, and most airway complications are the consequence of potential difficulties at mask ventilation or intubation due to specific anatomic features (eg, prognathism, large tongue, obesity).⁶

Conversely, critically ill patients are prone to a higher airway-related risk due to underlying hypoxaemia, shock or acidosis which expose them to a high incidence of adverse events, especially cardiovascular collapse, as recently reported in the INTUBE study cohort.^{7,8}

Data from large prospective studies on current incidence of major peri-intubation adverse events are lacking in the anaesthesia setting, especially outcomes such as peri-intubation cardiovascular collapse, severe hypoxaemia and cardiac arrest.

These events are more common when airway difficulty arises, so that first pass intubation failure significantly increases attendant risk.⁷ Moreover, it has been documented that even transient hypotension during general anaesthesia may have long-term consequences and may be associated with a worse outcome in patients undergoing non-cardiac surgery.^{9,10}

The primary aim of the study will be to assess the current incidence of major adverse events during advanced airway management for anaesthesia in patients undergoing elective or emergency surgery and in the setting of non-operating room anaesthesia. The secondary aim will be to assess the current practice of airway management during anaesthesia worldwide.

METHODS AND ANALYSIS

Study design

We designed a large international multicentre prospective observational cohort study including patients undergoing advanced airway management during anaesthesia.

Objectives

The primary objective will be to describe the current incidence of complications associated with advanced airway management in the anaesthesia setting.

The secondary objectives will be:

- ▶ To describe the current practice of advanced airway management in different patient categories.
- ▶ To describe the current practice of advanced airway management in different surgical procedures/specialties.

- ▶ To evaluate the current practice of advanced airway management across different geographical regions.

Inclusion criteria

We will include all consecutive adult (≥ 18 years) patients undergoing advanced airway management for general anaesthesia in operating room or non-operating room anaesthesia (NORA) locations. We will include patients undergoing advanced airway management, defined by tracheal intubation or supraglottic airway placement for either diagnostic or therapeutic procedures (table 1).

All potentially eligible patients will be identified by local investigators screening the operating room (OR) schedule and the procedures under general anaesthesia performed outside the OR.

Exclusion criteria

Patients undergoing advanced airway management as a component of the treatment of their underlying critical illness (table 1).

OUTCOMES

Primary outcome

At least one of the following major adverse events occurring within 30 min from the start of induction or up to surgical incision, whichever is first:

- ▶ Severe hypoxaemia ($\text{SpO}_2 < 80\%$).
- ▶ Cardiovascular collapse (at least one of the following):
 - Systolic arterial pressure < 65 mm Hg.
 - Systolic arterial pressure < 90 mm Hg for > 15 min.
 - Unplanned need of vasopressors and/or fluid load > 15 mL/kg to maintain target blood pressure.
- ▶ Cardiac arrest.

Blood pressure values should be confirmed in two consecutive measurements by non-invasive blood pressure monitoring or in two consecutive measurements 10 s apart using invasive blood pressure monitoring.

Secondary outcomes

- ▶ Minor adverse events:
 - Moderate hypoxaemia ($\text{SpO}_2 < 93\%$).
 - Airway injury.
 - Clinically relevant airway bleeding.
 - Aspiration of gastric contents.
 - Dental injury.
- ▶ Difficult facemask ventilation.

Table 1 Inclusion and exclusion criteria of the STARGATE study

Inclusion criteria	<ul style="list-style-type: none"> ▶ Consecutive patients undergoing advanced airway management (ie, supraglottic airway device placement or tracheal intubation) for general anaesthesia in either operating room or for non-operating room anaesthesia ▶ Age ≥ 18 years
Exclusion criteria	Patients undergoing advanced airway management as a component of the treatment of their underlying critical illness

- ▶ First pass success rate.
- ▶ Early cardiovascular collapse.
- ▶ Late cardiovascular collapse.

Outcome definitions are included in [table 1](#) of the online supplemental material.

Other outcomes

- ▶ Unplanned need for Intensive Care Unit (ICU) admission secondary to airway management-related complications.
- ▶ Emergency front of neck access (eFONA).
- ▶ Post-procedure severe hypertension.
- ▶ Difficult intubation, defined as the need for more than two intubation attempts.
- ▶ Incidence of cannot intubate cannot oxygenate scenario (CICO).
- ▶ In-hospital mortality.

STUDY PROCEDURES AND SETTINGS

The study sponsor is the University of Turin, Italy. The study has been endorsed by several scientific societies including the European Society of Anaesthesia and Intensive Care (ESAIC), European Airway Management Society (EAMS), French Society of Anaesthesia and Critical Care (SFAR), Irish Perioperative Medicine Trial Group of the College of Anaesthesiologists of Ireland, Australian Society of Anaesthetists (ASA), Safe Airway Society (SAS, Australia and New Zealand), Croatian Society of Anaesthesiology, Reanimatology and Intensive Medicine (HDARIM), Hellenic Society of Anaesthesiology. Scientific Societies endorsing the study will promote participation of interested centres through their members' mailing lists and during scientific meetings. A study website has been launched to provide study information and collect contact details of colleagues interested in participation (www.stargatestudy.com).

The recruitment window opened on 15 January 2024 and is expected to conclude on 15 March 2026. The list of participating centres is included in online supplemental material 2.

The inclusion period will be flexible for participating centres. After obtaining local approval, each centre will select a date for screening of patients and recruitment to start. In order to avoid selection bias while addressing study feasibility and balance across different participating centres, a maximum number of 50 consecutive patients, 40 from operating room and 10 from non-operating room anaesthesia at each centre, will be enrolled. To maintain feasible data collection and optimise enrolment of all consecutive patients, especially for high-volume centres, we will recommend focusing screening for enrolment from a predefined number of operating rooms (3–5 according to local workload) up to the final enrolment of 40 consecutive patients/centre in the anaesthesia setting without any time limitation. All consecutive patients undergoing surgery (with or without advanced airway management) in the previously identified operating rooms will be prospectively screened

(eg, checking the daily operating list/schedule) and reported.

Similarly, all consecutive patients undergoing advanced airway management in the NORA setting will be screened up to the final enrolment of 10 patients/centre without any time limitation.

Screening and reporting of all consecutive patients will be interrupted only when the target number of patients/centre is reached. All screened patients, independently of their final inclusion, will be traced in an electronic screening log and reported.

DATA COLLECTION

All consecutive patients undergoing anaesthesia will be screened for eligibility from the start of the recruitment window at each centre.

Data will be collected in real time by an investigator not involved in airway management using either the paper or the electronic version of the case report form. Patients' demographic characteristics, comorbidities and laboratory data will be collected from the patients' medical records. [Figure 1](#) illustrates the study diagram.

The following data will be collected:

- ▶ Centre characteristics (number of beds, availability of a protocol for airway management, adoption of cognitive aids, formal training of operators performing advanced airway management procedures).
- ▶ Screening data for eligibility.
- ▶ Reason for exclusion of an eligible patient.
- ▶ Informed consent and admission data.
- ▶ Demographic and comorbidities.
- ▶ Type of procedure (time, setting, type of surgery, elective or emergency).
- ▶ Airway assessment (anticipated difficult airway management).
- ▶ Monitoring applied during induction of anaesthesia.
- ▶ Patient's physiological parameters before induction.
- ▶ Preoxygenation method.
- ▶ Fraction of expired O₂ (FeO₂) at the end of preoxygenation.
- ▶ Drugs used for induction (agents and doses).
- ▶ Initial method for advanced airway management.
- ▶ Operator's characteristics.
- ▶ Method used for the second (or following) attempts.
- ▶ Method used for adequate tube placement confirmation.
- ▶ Duration of the airway management procedure.
- ▶ Outcome of airway management procedure (total number of attempts, laryngoscopy view, minimum SpO₂ during the procedure, need for rescue strategies).
- ▶ Advanced airway management-related complications (severe cardiovascular collapse, severe and mild hypoxaemia, cardiac arrest, airway injury or any bleeding, aspiration of gastric contents, dental injury,

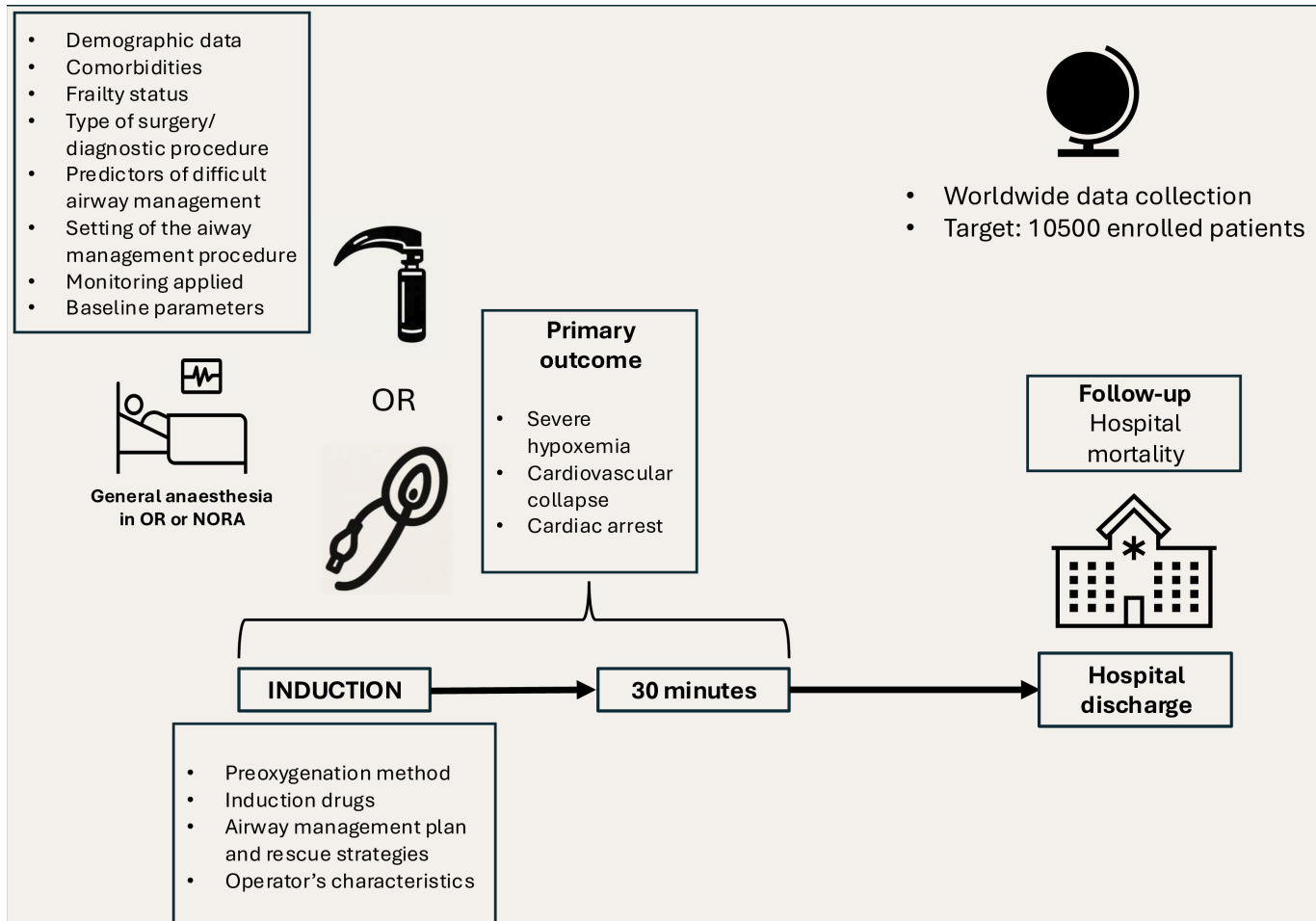


Figure 1 Study diagram. NORA, non-operating room anaesthesia; OR, operating room.

eFONA, CICO, unplanned need for ICU admission secondary to airway management complications).

- ▶ Extubation procedure and place.
- ▶ In-hospital mortality.

DATA MANAGEMENT

Anonymised data will be collected in a web-based electronic case report form (eCRF, REDCap—Research Electronic Data Capture) hosted at University of Turin, Italy. A local investigator will receive personal login credentials for data entry. A two-step login procedure will be implemented to enhance security. Each patient will be identified by a centrally generated code. The database will be securely stored by the University of Turin, Italy. All procedures of data collection and management will comply with the EU Regulation 2016/679 (General Data Protection Regulation) on the protection of natural persons with regard to the processing of personal data and on their transfer.

SAMPLE SIZE

Post-intubation hypotension has been reported in up to 10% of patients.^{9 11 12}

We aim to collect data on 1000 major events during advanced airway management in order to include at least

10 putative variables associated with this event in planned analyses and subanalyses; therefore, we plan to recruit a total of 10 000 patients. Considering a 5% data loss, our final sample size will be 10500 patients. We estimated an average number of 50 intubations/week at each centre, so we intend to recruit a total number of 210 centres.

STATISTICAL ANALYSIS

We will report mean and SD of normally distributed variables, and we will compare them using the Student's t-test. We will report non-normally distributed variables as median and IQR, comparing them using the Mann-Whitney U test. Categorical variables will be expressed as proportions and compared using the χ^2 or Fisher exact test as appropriate. We will perform a univariable analysis to identify variables associated with the composite outcome of major peri-intubation adverse events, and variables will then be selected to construct a multivariable logistic model in order to identify independent variables.

The following planned secondary analyses will be performed:

- ▶ Site of intubation: OR vs NORA

- ▶ Type of surgery: cardiac vs non-cardiac surgery, ear-nose-throat surgery, thoracic surgery
- ▶ Urgency of the procedure: planned advanced airway management vs unplanned advanced airway management
- ▶ Type of hypnotic drug used: propofol vs alternative drugs
- ▶ Airway management procedure: difficult airway management vs not difficult
- ▶ Patient's condition:
 - American Society of Anaesthesiologists (ASA) 1–2 versus ASA 3–4.
 - Body Mass Index (BMI) <30 versus BMI >30.

A two-sided p value <0.05 will be considered statistically significant. Statistical analysis will be performed using R 3.6.2 (<http://www.R-project.org>).

ETHICAL CONSIDERATIONS

The study has been approved by the Ethics Committee of the coordinating centre (Comitato Etico Interaziendale AOU San Luigi Gonzaga, N° 25/2023). Each of the participating centres will then submit the request for approval to their local Ethics Committee before starting enrolment, with either the patient's written consent or waiver of consent for participation according to local regulations. The Principal Investigator and the Steering Committee will guarantee that the study will be conducted with full adherence to the Declaration of Helsinki and Good Clinical Practices.¹³

DISSEMINATION

Data will be disseminated to the scientific community by original articles submitted to international peer-reviewed journals.

AUTHORSHIP POLICIES

The authorship policy will follow the International Committee of Medical Journal Editors (ICMJE) recommendations. Authorship will be considered based on contributions to study conception and design, data acquisition and cleaning, analysis and interpretation of the data, manuscript writing, submission of national/local grants, final approval of the version to be published and agreement to be accountable for all aspects of the work, in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Members of the Steering Committee will be part of the Writing Committee and listed as study authors. National Coordinators fulfilling the previously agreed criteria will be considered potentially eligible for the writing committee.

Local investigators will be listed as study collaborators in proportion to the number of patients recruited

in each centre and identified as STARGATE Study Collaborators.

SUBSTUDY PROPOSALS

After publication of the primary results, on request, the dataset will be available to investigators for secondary analyses, after submission of a substudy proposal which will be evaluated for approval by the Steering Committee after consideration of its scientific quality (ie, originality and scientific relevance).

PATIENT AND PUBLIC INVOLVEMENT

Patients and/or the public were not involved in this study.

DISCUSSION

STARGATE will be a large prospective international cohort study designed to obtain a detailed description of relevant adverse outcomes during advanced airway management in anaesthesia and NORA settings.

To our knowledge, it will be the largest prospective international cohort study investigating airway management and its association with the *physiological* outcomes of cardiovascular collapse, severe hypoxaemia and cardiac arrest in this setting. Peri-intubation cardiovascular collapse is the leading adverse event in critical care, reported in up to 43% of patients, followed by severe hypoxaemia in 9% and cardiac arrest in 3% of patients in the INTUBE cohort.⁷

Peri-intubation hypotension is also a common event in the anaesthesia setting, although data from international cohorts are lacking. Induction of anaesthesia is a critical period as up to one-third of intraoperative hypotensive events have been reported during induction of general anaesthesia for elective non-cardiac surgery, and hypotension occurring either before or after skin incision was associated with increased risk of acute kidney injury.⁹

Both unmodifiable (eg, older age, ASA physical status) and modifiable factors (eg, induction agent selection) have been associated with a higher risk of post-induction hypotension.¹⁴ The important vasodilation and negative inotropic effect of propofol¹⁵ may have an important role on post-induction hypotension and results from the STARGATE study may be informative about this effect in a large prospective patient cohort.

Perioperative hypotension has been associated with an increased perioperative morbidity, with post-operative acute kidney injury, myocardial injury, stroke and delirium as the most commonly reported patient's outcomes.¹⁰ Additionally, increasing age, carrying a higher number of comorbidities and frailty status in patients scheduled for surgical and diagnostic procedures may increase the susceptibility to adverse events during airway management and their long-term clinical consequences.^{10,16} In a recently published retrospective single-centre study, prefrail and frail patients aged ≥70 years experienced

up to 28% more hypotensive events during anaesthesia induction compared with more robust patients.¹⁶ The STARGATE study will examine patient and procedural factors associated with adverse events in a large real-life cohort, and it will inform clinicians and researchers regarding high-priority knowledge gaps of strategies to mitigate risks. Examples of these strategies may involve enhancing physiological reserve by preoperative rehabilitation, better selection of haemodynamic monitoring for vulnerable patient groups (eg, preinduction start of invasive monitoring), a tailored selection of induction agents and dosing, and of the airway management plans.^{14 16} Given the high volume of surgical procedures performed under general anaesthesia each year worldwide, and the growing number and complexity of NORA procedures, identification of lower risk interventions and their personalisation for more vulnerable patients may have major impact on healthcare systems.¹⁷

Large international studies provide the opportunity to gauge how evidence-based interventions are routinely implemented in real life.¹⁸ In the INTUBE study, conducted in the critical care setting, only 51% of procedures used a standard protocol and, as an example of poor application of an evidence-based intervention, only 25.6% of intubations were confirmed by waveform capnography.⁷ Similarly, we suspect that, in the anaesthesia setting, significant heterogeneity in the practice of airway management across different geographical areas exists, in addition to inadequate implementation of some evidence-based interventions and guidelines recommendations.

Airway management during NORA has been considered a higher risk compared with procedures performed in the operating room.¹⁹ This increased risk has been attributed to different factors including patient and procedure characteristics (eg, prone or lateral positions, limited access to patients' airways), remote and less familiar locations, less experienced personnel, poor availability of devices (eg, for monitoring or as a rescue strategy in case of failed airway management).¹⁹ The STARGATE study will collect data from this high-risk setting that will be useful to identify knowledge gaps and safety priorities.

Finally, we will collect large-scale information on operators' training and background, on strategies to maintain skills and to avoid/overcome airway crises.

The STARGATE study has several strengths. First, its prospective design will limit the effect of confounding, which may negatively influence retrospectively designed studies. Second, the large sample size will be able to provide data on relatively rarely performed procedures or events associated with airway management (eg, difficult intubation, adoption of rescue strategies, other rare complications). Third, the inclusion of centres from different geographical areas with different resource levels will make the study findings more generalisable.

The main limitation of this study is its observational design, with the consequent difficulty in inferring causation among associations, and the potential

influence of unmeasured confounders. The primary aim of the study is, however, to describe the epidemiology of adverse events associated with airway management practice during anaesthesia and identify knowledge gaps for future research.

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