# AWARE - AWAke tRachEal intubation

## An International Multicenter Survey

### Background

International guidelines focus on the need to ensure patient oxygenation during airway management [1-2] and recommend awake tracheal intubation (ATI) as the gold standard technique for anticipated difficult intubation, and recently guidelines have been published[3].

Observational studies, however, suggest that awake tracheal intubation procedures are performed less often than suggested by guidelines, with a progressively decreasing frequency [4-5]. The increasing availability of video laryngoscopes is changing clinical practice by reducing the use of this approach in contrast with international recommendations on airway management[6].

This may result in an increased risk of mortality and morbidity in patients with expected difficult airways[7]. Furthermore, the lack of experience and expertise with equipment or limited skills in ATI, might also contribute to avoidance of ATI despite clear indications[2].

Last but not least, lack of specific information about ATI awareness and performance does not allow any opportunity of corrective and educational interventions.

### Aim of the study

This observational study aims to evaluate, the frequency of use of ATI in current clinical practice.

We focus on ATI knowledge, frequency and modality when routinely used, potential factors for and against its use. We also investigate any needs and suggestions on how ATI technique could be promoted, taught and, consequently, implemented in clinical routine.

### Methods

A committee of Airway Management experts in collaboration with the European Airways Management Society (EAMS) and the Anaesthesia Department of the University in Turin, Italy developed a questionnaire consisting of 37 multiple choice questions divided into four sections. The questionnaire will be disseminated worldwide through social media with a 'snowballing' sampling technique. Selection bias will be reduced by collecting responses from at least 100 countries. The online questionnaire will collect only anonymized data Filling the survey will be considered as consent for participation and use of the anonymised data entered for the study. We estimate the data collection period to be 6 months with a series of in-itinere reminders.

It has already received the endorsement/support by All India Difficult Airway Association (AIDAA), Polish Anesthesiology and Intensive Therapy Society, Associazione Anestesisti Rianimatori Ospedalieri Italian (AAROI), German Society of Anaesthesiology and Intensive Care Medicine (DGAI), Czech Society of Anaesthesiology and Intensive Care, Chilean Society of Anesthesiology

and Polish Society of Anesthesiology and Intensive Therapy. Many other Societies endorsement are ongoing.

Inclusion criteria

All anesthetists (in training and specialists) who can understand English and have Internet access to the Survey Monkey platform are eligible to complete the questionnaire from all genders and countries worldwide and who provide informed consent to participate in the study.

Data handling and record keeping/archiving

Data will be collected anonymously. Only study investigators will have access to the data that will be stored on the Survey Monkey platform until the end of the study. After the closure of the recruitment data will be transferred to a computer of the coordinating study center and will be kept in a password-protected file for 10 years according to the Italian law on human research.

**Statistics**

Sample Size Calculation: we started with a previously reported approach[8] that aimed to get responses from up to 10% of each national anaesthesia society's members, or five responses per million inhabitants in a country with a 500 responses cut off. These estimates were compared with real life data[8] to get a realistic and achievable estimate. That revealed for this survey 7800 participants.

Statistical analysis: Data will be analyzed with the R software (R Foundation for Statistical Computing, Vienna, Austria). Results from multiple-choice questions will be presented as percentages while open questions will be analyzed qualitatively. Pearson's Chi square and Fisher's exact tests will be used for contingency tables accordingly to expected frequencies for categorical variables. A two-tailed p value $< 0.05$ will be considered statistically significant.

**GCP Statement and Ethical conduct of the study:**

This study will be conducted in compliance with the protocol, the Declaration of Helsinki, the ICH-GCP or ISO EN 14155, and all national legal and regulatory requirements. Since this observational study does not include patients and all data collected are anonymized, the ethics committee of the University of Turin waived the study registration and did not require participant's informed consent.

*Ethical considerations*

The potential gain of new knowledge obtained with this study, and its meaning for patients and society will come from insights on real-life data on ATI pointing out possible differences between international recommendations and local practice. These data might direct ways to increase compliance to algorithms, improving patient safety while managing a difficult airway. This survey does not imply any risks for patients as no patient's data are investigated, and the methodology follows established scientific practice for such investigations to gain new generalizable knowledge.

*Participant privacy and confidentiality*

The investigators affirm and uphold the principle of the participant's right to privacy and that they shall comply with applicable local privacy laws. Privacy of participants will be guaranteed when presenting the data at scientific meetings or publishing them in scientific journals. All obtained data during this study is considered confidential and no data will be transferred to third parties.

**Publication and dissemination policy**

The results will be published in a peer-reviewed international journal. The authors will be study team members contributing to the design, conduct or analysis, recruitment of survey responders. All authors will be involved in writing the manuscript and approve the final version. Authorship policy will follow the International Committee of Medical Journal Editors (ICMJE) recommendations**.**

**Study Administrative Structure (in progress):**

Coordinating Study Center: AOU Città della Salute e della Scienza, Turin, Italy
Study Sponsor: University of Turin, Italy
Primary Investigator: Gerardo Cortese
Co-Investigators: Imran Ahmad, Luca Brazzi, Robert Greif, George Kovacs, Adam Law, Sheila Myatra, Massimiliano Sorbello, Irene Steinberg
Collaborators: in process
Data Monitoring: University of Turin

## References


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