INPLASY PROTOCOL

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None declared.

Second-generation supraglottic airways vs endotracheal tubes in adults undergoing abdominopelvic surgeries: a protocol for a systematic review with pairwise meta-analyses of randomised clinical trials

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Review question / Objective: **We aim to compare second-generation supraglottic airways with endotracheal tubes for perioperative safety and quality of postoperative recovery as well as for ventilation performance and risk of pulmonary aspiration.**
Eligibility criteria: **Inclusion criteria will be as follows: randomized clinical trials; human patients aged ≥ 16 years undergoing abdominopelvic procedures under general anaesthesia from any population (e.g., general population, pregnant women, obese patients); data available on any outcome related to insertion performance (e.g., failed first attempt, failed insertion, and time to insertion), ventilation efficacy (e.g., leak pressure, leak fraction, and ventilation inadequacy), risk of regurgitation and aspiration (e.g., gastric insufflation, regurgitation, and aspiration), quality of postoperative recovery (e.g., sore throat, hoarseness, and postoperative nausea and vomiting [PONV]), and major complications (e.g., laryngospasm, bronchospasm, and hypoxemia); and comparison between any second-generation SGA and an endotracheal tube. We will exclude: studies reported in a language that prevent us of extracting relevant information; outcomes with no objective data presented (i.e., effect sizes, measures of dispersion, frequency, etc.); and studies with contradictory data.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 September 2022 and was last updated on 08 September 2022 (registration number INPLASY202290041).

INTRODUCTION

Review question / Objective: **We aim to compare second-generation supraglottic airways with endotracheal tubes for perioperative safety and quality of postoperative recovery as well as for**

ventilation performance and risk of pulmonary aspiration.

Condition being studied: We will evaluate perioperative safety and quality of postoperative recovery.

METHODS

Search strategy: PubMed: (Laryngeal Masks[mh] OR "laryngeal mask" OR supraglottic OR LMA OR i-gel OR proseal OR PLMA OR P-LMA OR supreme OR SLMA OR S-LMA OR igel OR i-gel OR cobra OR "streamlined linear of the pharynx airway" OR SLIPA OR "laryngeal tube" OR LT OR LTS OR auragain OR protector OR auraonce OR air-q OR softseal OR solus) AND (intubation[mh] OR intubation OR tube OR endotracheal OR tracheal)
Embase: ('laryngeal mask'/exp OR 'laryngeal mask' OR supraglottic OR 'lma'/exp OR lma OR 'proseal'/exp OR proseal OR plma OR 'p lma' OR 'supreme'/exp OR supreme OR slma OR 's lma' OR 'igel'/exp OR igel OR 'i gel'/exp OR 'i gel' OR 'cobra'/exp OR cobra OR 'streamlined linear of the pharynx airway' OR 'slipa'/exp OR slipa OR 'laryngeal tube'/exp OR 'laryngeal tube' OR lt OR lts OR 'auragain'/exp OR auragain OR protector OR 'auraonce'/exp OR auraonce OR 'air q'/exp OR 'air q' OR softseal OR 'solus'/exp OR solus) AND ('intubation'/exp OR intubation OR 'tube'/exp OR tube OR endotracheal OR tracheal)
Web of Science: ("laryngeal mask" OR supraglottic OR LMA OR i-gel OR proseal OR P-LMA OR supreme OR S-LMA OR i-gel OR cobra OR "streamlined linear of the pharynx airway" OR "laryngeal tube" OR LT OR LTS OR auragain OR protector OR air-q OR soleus) AND (intubation OR tube OR endotracheal OR tracheal)
Cochrane CENTRAL: ("laryngeal mask" OR supraglottic OR LMA OR i-gel OR proseal OR plea OR P-LMA OR supreme OR S-LMA OR igel OR i-gel OR cobra OR "streamlined linear of the pharynx airway" OR "laryngeal tube" OR LT OR LTS OR auragain OR protector OR air-q OR soleus) AND (intubation OR tube OR endotracheal OR tracheal).

Participant or population: Patients aged ≥ 16 years undergoing abdominopelvic procedures under general anaesthesia from any population (e.g., general population, pregnant women, obese patients).

Intervention: Second-generation supraglottic airways.

Comparator: Endotracheal tubes.

Study designs to be included: Randomized clinical trials only.

Eligibility criteria: Inclusion criteria will be as follows: randomized clinical trials; human patients aged ≥ 16 years undergoing abdominopelvic procedures under general anaesthesia from any population (e.g., general population, pregnant women, obese patients); data available on any outcome related to insertion performance (e.g., failed first attempt, failed insertion, and time to insertion), ventilation efficacy (e.g., leak pressure, leak fraction, and ventilation inadequacy), risk of regurgitation and aspiration (e.g., gastric insufflation, regurgitation, and aspiration), quality of postoperative recovery (e.g., sore throat, hoarseness, and postoperative nausea and vomiting [PONV]), and major complications (e.g., laryngospasm, bronchospasm, and hypoxemia); and comparison between any second-generation SGA and an endotracheal tube. We will exclude: studies reported in a language that prevent us of extracting relevant information; outcomes with no objective data presented (i.e., effect sizes, measures of dispersion, frequency, etc.); and studies with contradictory data.

Information sources: We have already conducted searches in PubMed, Embase, Web of Science, and Cochrane Central Register of Controlled Trials (CENTRAL) on 30 June 2022.

Main outcome(s): Our primary outcomes are perioperative complications: postoperative sore throat, hoarseness, dysphagia, tissue damage, PONV within 24

hours of the end of anaesthesia, and abdominopelvic pain within two hours of the end of anaesthesia; as well as major complications during the perioperative period such as laryngospasm, bronchospasm, and hypoxemia.

Additional outcome(s): Our secondary outcomes are any outcome available related to insertion performance (e.g., failed first attempt, failed insertion, and time to insertion), ventilation efficacy (e.g., leak pressure, leak fraction, and ventilation inadequacy), and risk of regurgitation and aspiration (e.g., gastric insufflation, regurgitation, and aspiration).

Quality assessment / Risk of bias analysis: We will judge in duplicate the risk of bias in individual studies for each outcome according to the Cochrane Risk of Bias 2 tool. Five domains are assessed through this tool: randomization process; deviation from intended intervention; missing outcome data; measurement of the outcome; and selection of reported results. An overall risk of bias assessment will also be performed.

Strategy of data synthesis: We will conduct pairwise meta-analyses using R software tools (R Foundation for Statistical Computing, Vienna, Austria). Data will be summarized if there are at least two studies available. Per-protocol raw outcome data (i.e., not pre-calculated effect sizes) will be extracted or calculated from studies and summarized. Effect sizes, standard errors, and 95% CI will be estimated for each study. Forest plots of relative risk or mean difference will be produced for every outcome. Pooled effects will be calculated from random-effects or fixed-effects models, as appropriate. Heterogeneity will be evaluated quantitatively by Cochran's Q test and I2. Influence analyses will be performed to assess the influence of each study on the pooled effects and the heterogeneity between studies as well as to evaluate the influence of outliers on the summarized results. The small sample bias method will be used to assess the risk of publication bias where 10 or more studies are available. Funnel plots will be constructed and Egger's test of asymmetry performed. The threshold of significance will be set at $p < 0.1$ for this method as this test has low power. A Durval and Tweedie's trim-and-fill procedure will be applied to estimate bias-corrected effects.

Subgroup analysis: A subgroup analysis will be performed when the sensitivity analyses present significant influence of a variable over the summarized results and there is sufficient data for the subgroup summarization. Variables to be assessed: operator experience; population; risk of bias; and presence of outliers.

Sensitivity analysis: Sensitivity analyses will be conducted accounting for the following variables: operator experience; population; risk of bias; and presence of outliers.

Language restriction: No limitations were applied to the searches.

Country(ies) involved: Brazil and United Kingdom.

Keywords: airway management; intubation, intratracheal; laryngeal masks; supraglottic airways; systematic review.

Dissemination plans: We plan to publish our results in a peer-reviewed scientific journal.

Contributions of each author:

Author 1 - Clístenes Crístian de Carvalho - CCC conceived the study, designed the methods, and drafted the protocol.
Email: clistenescristian@hotmail.com
Author 2 - Ioannis Kapsokalyvas - IK reviewed the protocol and approved it.
Author 3 - Kariem El-Boghdadly - KE reviewed and helped design the methods, and approved the final protocol.