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Comparison of the airway complications of subtypes of laryngeal mask airway and i-gel in child patients under general anaesthesia: a protocol for systematic review and network meta-analysis of randomised control trials

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ABSTRACT

Introduction Laryngeal mask airway (LMA), an alternative to traditional tracheal intubation, is widely used in clinical practice and is considered to be an effective device for airway management. LMA and i-gel have been widely used in anaesthesia and emergency situations in children. Some systematic reviews have evaluated the efficacy of LMA and i-gel in children, but they have not shown consistent results in clinical performance. This study aims to evaluate the airway complications of all subtypes of LMA and i-gel in child patients under general anaesthesia using a Bayesian network meta-analysis (NMA).

Methods and analysis PubMed, EMBASE.com, the Cochrane library, Web of Science and Chinese Biomedical Literature Database will be searched from inception to January 2019. We will include prospective randomised controlled trials (RCTs) that reported the subtypes of LMA and i-gel regardless of sample size. The risk of bias assessment of the included RCTs will be conducted according to the Cochrane Handbook V.5.1.0. A Bayesian NMA will be performed using WinBUGS V.1.4.3. Grading of Recommendations Assessment, Development and Evaluation will be used to explore the quality of evidence.

Ethics and dissemination Ethics approval and patient consent are not required as this study is an NMA based on published trials. The results of this NMA will be submitted to a peer-reviewed journal for publication.

PROSPERO registration number CRD42019127668.

Strengths and limitations of this study

- This study will be the first network meta-analysis comparing the airway complications of subtypes of laryngeal mask airway and i-gel in child patients under general anaesthesia.
- Two reviewers will independently conduct the study selection, data extraction and quality assessment.
- The quality of evidence will be assessed by the Grading of Recommendations Assessment, Development and Evaluation system.
- Both pairwise meta-analysis and network meta-analysis will be performed.
- Our results will be limited by the number of available trials and the quality of included trials.

INTRODUCTION

In 1983, Brainhas introduced the new concept in airway management-laryngeal mask, but the laryngeal mask airway (LMA) was introduced in 1988 in the USA.[1 2] The LMA gained a wide application in clinical practice as an alternative to traditional tracheal tube intubation and is considered as an effective device for airway management if face mask ventilation and intubation failed or are expected to be unfeasible due to airway malformations or to the specific work setting.[3–5] At the same time, LMA has been demonstrated to be easily placed by medic and paramedic staff.[6]

A variety of LMAs has been introduced in the field of anaesthesia and emergency situations in child patients. Compared with most LMAs with an inflatable cuff, on the contrary, i-gel is one of the second generation and a relatively newer addition to the armamentarium of supraglottic airways. I-gel is different from all other laryngeal masks in that it does not have an inflatable cuff, rather, i-gel has a soft gel-like cuff that is made of medical-grade transparent thermoplastic elastomer that does not require inflation.[7 8] Previous systematic reviews (SRs) or meta-analyses in the field of anaesthesia did not show consistent results in the clinical performance.[9 10] At the same time, significant risk factors for postoperative airway complications related to the use of different subtypes of LMA or i-gel in child patients, which are not assessed by the network meta-analysis (NMA).

NMA has been considered to extend conventional meta-analysis on multiple treatments for a given condition.[11 12] As we know, well-conducted SRs and meta-analyses of randomised controlled trials (RCTs) are often considered the best way to obtain evidence of healthcare decisions.[13–16] Compared with pairwise meta-analyses, NMAs allow for visualisation of a larger amount of evidence, estimation of the relative effectiveness among all interventions (even if some head to head comparisons are lacking) and rank ordering of the interventions.[17] The value of NMAs for healthcare decision making has been recognised and accepted by different health technology assessments and funding agencies worldwide.[18] Therefore, we will conduct an SR and NMA to evaluate the airway complications of all subtypes of LMA and i-gel in child patients under general anaesthesia.

METHODS

The current NMA will be conducted by following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.[19]

Eligibility criteria

Type of study

We will include prospective RCTs that reported the subtypes of LMA and i-gel regardless of the sample size.

Type of patients

Child patients are younger than 18 years of age under general anaesthesia.

Type of interventions

All subtypes of LMAs will be included: Classic LMA, Fastrach LMA, Proseal LMA, Unique LMA, Flexible Reinforced LMA and Supreme LMA.

Type of outcomes

The primary outcome will be the incidence of airway complications, which will be related to the choice of device size of cuff, including sore throat, dysphagia, dysphonia, cough, blood on device, lip trauma and laryngospasm. The second outcome will include specific types of airway complications if data are available.

Data sources

PubMed, EMBASE.com, the Cochrane Library, Web of Science and Chinese Biomedical Literature Database will be searched from inception to 31 January 2019. At the same time, the reference lists of published reviews and retrieved articles will be checked for additional trials.

Study selection

Two review authors will independently screen titles and abstracts of each record retrieved by EndNote X8 (Thomson Reuters (Scientific) Philadelphia, Pennsylvania, USA). Then, full texts of all potentially relevant studies will be obtained and reviewed for further assessment. Disagreements will be discussed or by a third reviewer if no consensus is reached. We will use a predefined extraction form with detailed written instructions which will be created using Microsoft Excel 2013 (Microsoft, Redmond, Washington, USA, www.microsoft.com) to collect relevant information and data.[20] Data will be extracted from eligible studies including publication details, participant details, device details, surgery details, airway complications and risk of bias. Any missing data will be acquired by contacting the author by email (table 1).

Table 1 Full data extraction table

Item	Content
Publication details	Name of author
	Year of publication
	Name and impact factor of journal
Participant details	American Society of Anesthesiologist Classification
	Sex
	Age
	No of participants
	Setting
Device details	Type of device
	Methods of selection device size
Surgery details	Time of surgery
	Type of surgery
Airway complications	Method of registration of airway complications
	Time of airway complications
	Sore throat
	Dysphagia
	Dysphonia
	Cough
	Blood on device
	Laryngospasm
	Other
Risk of bias	Random sequence generation
	Allocation concealment
	Blinding of participants and personnel
	Blinding of outcome assessment
	Incomplete data
	Selective outcome reporting
	Other bias

Search strategy

The key search terms are laryngeal mask, laryngeal mask airway, LMA, i-gel, and their synonyms. Full details of the search strategies can be found in online supplementary appendix 1. Search strategy of PubMed as follows:

#1 "Laryngeal Masks"[Mesh] OR laryngeal mask airway*[Title/Abstract] OR laryngeal mask*[Title/Abstract] OR aryngeal mask*[Title/Abstract] OR arynx mask*[Title/Abstract] OR LMA[Title/Abstract]

#2 i-gel[Title/Abstract] OR igel[Title/Abstract] OR i gel[Title/Abstract]

#3 #1 OR #2

#4 "Clinical Trials, Phase II as Topic"[Mesh] OR "Clinical Trials, Phase III as Topic"[Mesh] OR "Clinical Trials, Phase IV as Topic"[Mesh] OR "Controlled Clinical Trials as Topic"[Mesh] OR "Randomized Controlled Trials as Topic"[Mesh] OR "Intention to Treat Analysis"[Mesh] OR "Pragmatic Clinical Trials as Topic"[Mesh] OR "Clinical Trials, Phase II"[Publication Type] OR "Clinical Trials, Phase III"[Publication Type] OR "Clinical Trials, Phase IV"[Publication Type] OR "Controlled Clinical Trials"[Publication Type] OR "Randomized Controlled Trials"[Publication Type] OR "Pragmatic Clinical Trials as Topic"[Publication Type] OR "Single-Blind Method"[Mesh] OR "Double-Blind Method"[Mesh]

#5 random*[Title/Abstract] OR blind*[Title/Abstract] OR singleblind*[Title/Abstract] OR doubleblind*[Title/Abstract] OR trebleblind*[Title/Abstract] OR tripleblind*[Title/Abstract]

#6 #4 OR #5

#7 #3 AND #6

Risk of bias of individual studies

Two reviewers will independently use the Cochrane Handbook V.5.1.0 for SRs of intervention to assess the quality of included RCTs.[21] We will resolve any disagreement by discussion or by involving a third review author. The Handbook includes random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other sources of bias. We will rate the methodological quality as low, high or unclear risk of bias. Bias in RCTs will be evaluated for seven items: method of random sequence generation (selection bias), allocation concealment (selection bias), participant and personnel blinding (performance bias), outcome assessment blinding (detection bias), incomplete data (detection bias), selective reporting (detection bias) and other bias. Each item will be classified as high, low or unclear risk of bias.

Geometry of the evidence network

A network plot will be created to describe and present the geometry of the intervention network of comparisons across trials using STATA (V.13.0; Stata). If a pair of interventions are not connected to the rest of the network, we will exclude those interventions from the NMA and describe that comparison separately. In the network diagram, each node represents an intervention, and the edges represent head-to-head comparisons between a pair of interventions. The size of a node reflects the sample size for the intervention, and the thickness of an edge reflects the number of trials that included the comparison.

Statistical analysis

Pairwise meta-analyses

For airway complications, we will calculate the average OR and the 95% CI with the random effects using a mixed-effects logistic regression model.[22] We will not assess the statistical heterogeneity within each pairwise comparison using the I^2 because it has no useful interpretation.[22–24]

Network meta-analysis

The NMA will be performed in a Bayesian hierarchical framework using Markov Chain Monte Carlo method in WinBUGS V.1.4.3 (MRC Biostatistics Unit, Cambridge University, UK).[25] If the network contains any loops connecting three or more interventions, we will use the node-splitting method to examine inconsistency between direct and indirect evidence for each loop.[26 27] To rank the treatments according to each outcome accounting for the uncertainty in the treatment effects, we will use the surface under the cumulative ranking curve.[28] The absolute rank of the treatment per outcome is presented using 'rankograms' that visually show the distribution of ranking probabilities.[28] All the result figures will be generated using STATA (V.13.0) software.

Subgroup analysis

If the necessary data are available, subgroup analyses will be done for both pairwise meta-analyses and NMAs according to different types of participants by gender, country and device size of cuff.

Assessment of publication bias

Begg's and Egger's funnel plot methods will be performed to help distinguish asymmetry due to publication bias when applicable.[29 30]

Quality of evidence

We will assess the quality of the evidence using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach as outlined in the GRADE handbook in order to assess the quality of the body of evidence. The GRADE approach uses five considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of the body of evidence for each outcome. The overall quality is classified into four levels: high level, moderate level, low level and very low level.[31]

PATIENT AND PUBLIC INVOLVEMENT

Patients and the public were not directly involved in the design or planning of the study.

ETHICS AND DISSEMINATION

This study will summarise and provide evidence of airway complications in the subtypes of LMA and i-gel in child

patients under general anaesthesia. The results will be submitted to a peer-reviewed journal for publication. We hope the results of this NMA will help clinicians and patients to select an optimal laryngeal mask.

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Contributors JL and KY planned and designed the research. JL, XX, ML, RC and KY tested the feasibility of the study. JL and KY provided methodological advice, polished and revised the manuscript. JL, XX and KY wrote the manuscript. All authors approved the final version of the manuscript.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval Ethics approval and patient consent are not required as this study is a network meta-analysis based on published trials.

Provenance and peer review Not commissioned; externally peer reviewed.

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