BMJ Open

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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-032691
Article Type:	Protocol
Date Submitted by the Author:	01-Jul-2019
Complete List of Authors:	Liu, Jieting; Lanzhou University Second Hospital, Department of Anesthesiology Xu, Xiaonan; Lanzhou University Second Hospital, Department of Anesthesiology Li, Muyang; The Second Clinical Medical College of Lanzhou University Cai, Runjin; The Second Clinical Medical College of Lanzhou University Yang, Kehu; evidence based meidicine center, lanzhou university
Keywords:	Airway complications, laryngeal mask airway, i-gel, general anesthesia, child, network meta-analysis

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

Jieting Liu,[1] Xiaonan Xu,[1] Muyang Li,[2] Runjin Cai,[2] Kehu Yang,[3,4*]

[1] Department of Anesthesiology, Second Hospital of Lanzhou University, Lanzhou, China

[2] The Second Clinical Medical College of Lanzhou University, Lanzhou, China

[3] Evidence-Based Medicine Center, School of Basic Medical Sciences, Lanzhou University, Lanzhou, China

[4] Key Laboratory of Evidence-Based Medicine and Knowledge Translation of Gansu Province, Lanzhou, 730000, China

[*] **Correspondence to:** Evidence-Based Medicine Centre, School of Basic Medical Sciences, Lanzhou University; Key Laboratory of Evidence-Based Medicine and Knowledge Translation of Gansu Province, No.199, Donggang West Road, Lanzhou City, 730000, Gansu Province, China. (Email: kehuyangebm2006@126.com).

Abstract

Introduction Laryngeal mask airway (LMA), which is widely used as 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 anesthesia

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 anesthesia using a Bayesian network meta-analysis.

Methods and analysis PubMed, EMBASE.com, the Cochrane library, Web of Science, and Chinese Biomedical Literature Database were searched from inception to January 2019. We will include prospective randomized controlled trials (RCTs) that reported the subtypes of laryngeal mask airway and i-gel regardless of sample size. Risk of bias assessment of the included RCTs will be conducted according to the Cochrane Handbook 5.1.0. A Bayesian NMA will be performed using WinBUGS 14. GRADE will be used to explore the quality of evidence.

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

PROSPERO registration number: CRD42019127668.

Keywords: Airway complications, laryngeal mask airway, i-gel, general anesthesia, child, network meta-analysis

Strengths and limitations of this study

- To the best of our knowledge, this will the first network meta-analysis comparing the airway complications of subtypes of laryngeal mask airway and i-gel in child patients under general anesthesia.

- The results of this network meta-analysis will help clinicians and patients to select an optimal laryngeal mask.
- Our results will be limited by the number available trials and the quality of included trials.

1. Introduction

In 1983, Brain AI has introduced the new concept in airway management-laryngeal mask, but the laryngeal mask airway (LMA) was introduced in 1988 in the United States[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 have both 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 anesthesia and emergency situations in child patients. Compared to 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]. Based on the published systematic review or meta-analysis in the field of anesthesia, there were 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).

Network meta-analysis has been considered to extend conventional meta-analysis on multiple treatments for a given condition[11,12]. As we know, well-conducted systematic reviews (SRs) and meta-analyses of randomized 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 visualization 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 health-care decision making has been recognized and accepted by different health technology assessment and funding agencies worldwide [18]. Therefore, we conducted a systematic review and network meta-analysis to evaluate the airway complications of all subtypes of laryngeal mask airway and i-gel in child patients under general anesthesia.

2. Methods

The current network meta-analysis will be conducted by following the Preferred Reporting Items for network meta-analyses guidelines[19]. The protocol for this network meta-analysis has been registered on PROSPERO (International Prospective Register of Systematic Reviews). The registration number is CRD42019127668.

2.1. Eligibility criteria

2.1.1. Type of study. We will include prospective randomized controlled trials that reported the subtypes of laryngeal mask airway and i-gel regardless of sample size.

2.1.2. Type of patients. Child patients under general anesthesia.

2.1.3. Type of interventions. All subtypes of LMAs will be included such as Classic LMA, Fastrach LMA, Proseal LMA, Unique LMA, Flexible Reinforced LMA, and Supreme LMA.

2.1.4. Type of outcomes. The primary outcome will be the incidence of airway complications, which will be related to the choice of device size and the method of cuff inflation, including sore throat, dysphagia, dysphonia, cough, blood on device, and laryngospasm.

2.2. Data sources

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

2.3. Study selection

Two review authors will independently screen titles and abstracts of each record retrieved by EndNote X8 (Thomson Reuters (Scientific) LLC Philadelphia, PA, US). 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 was reached. We will use predefined extraction forms with detailed written instructions which will be created using Microsoft Excel 2013 (Microsoft Corp, Redmond, WA, 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 E-mail (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
	number of participants
	setting
Device details	type of device
	methods of selection device size
	methods of cuff inflation
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

2.4. Search strategy

The key search terms are laryngeal mask, laryngeal mask airway, LMA, i-gel, and their synonyms. 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

2.5. Risk of bias of individual studies

Two of reviewers will independently use the Cochrane Handbook V.5.1.0 for systematic reviews 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 consists of 6

domains: random sequence generation, allocation concealment, blinding of all participants, including patients, personnel and outcome assessors, incomplete outcome data, selective reporting, and other sources of bias. We will evaluate the methodological quality as low, high or unclear risk of bias. Bias in RCTs will be evaluated for 7 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 having a high, low, or unclear risk of bias.

2.6. Geometry of the network

A network plot to will be created to describe and present the geometry of the intervention network of comparisons across trials using STATA (13.0; Stata Corporation, College Station, Texas, USA). If the trial is not linked by interventions, we will exclude it from network meta-analysis and just describe the findings of the study. In the network plot, nodes represent different interventions and edges represent a head-to-head comparison between interventions. The size of the nodes and the thickness of the edges are associated with the sample size of the intervention and the number of trials included, respectively.

2.7 Statistical analysis

2.7.1 Pairwise meta-analyses. For airway complications, we will calculate the average odds

ratio with the 95% confidence interval (95% CI), We will assess statistical heterogeneity within each pair-wise comparison using the I^2 statistic and its 95% CI that measures the percentage of variability that cannot be attributed to random error[21]. If the P value ≥ 0.1 and $I^2 \leq 50\%$, it suggests that there is no statistical heterogeneity, and the Mantel Haenszel fixed effects model will be used for meta-analysis. If the P value < 0.1 and $I^2 > 50\%$, we will explore sources of heterogeneity by subgroup analysis and meta-regression. If there is no clinical heterogeneity, the random effects model will be used to perform the meta-analysis. Otherwise, clinical heterogeneity will be explored through discussion with the review team.

2.7.2 Network meta-analysis. The NMA will be performed in a Bayesian hierarchical framework using Markov Chain Monte Carlo method in WinBUGS 14 (MRC Biostatistics Unit, Cambridge University, UK)[18,22]. We will use the node splitting method to examine the inconsistency between direct and indirect comparisons if a loop connecting 3 or more arms exist[23]. To rank the treatments according to each outcome accounting for the uncertainty in the treatment effects, we used the surface under the cumulative ranking curve (SUCRA)[23]. The absolute ranks of the treatments per outcome is presented using 'Rankograms' that visually show the distribution of ranking probabilities [24]. A network plot will be drawn to describe and present the geometry of the treatment network of comparisons across trials to ensure if a network meta-analysis is feasible. All the result figures will be generated using STATA (13.0; Stata Corporation, College Station, Texas, USA Stata) software.

2.7.3. Subgroup analysis. If the necessary data are available, subgroup analyses will be done

for different types of participants by gender, country.

2.8. Assessment of publication bias.

Begg's and Egger's funnel plot method will be performed to help distinguish asymmetry due to publication bias when applicable[25-26].

2.9. Quality of evidence

We will assess the quality of the evidence using the 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. It is classified into 4 levels: high level, moderate level, low level, and very low level[15,27].

3. Ethics and dissemination

Ethics approval and patient consent are not required as this study is a network meta-analysis based on published systematic reviews. This study will summarize and provide evidence of airway complications in the subtypes of laryngeal mask airway and i-gel in child patients under general anesthesia. The results will be submitted to a peer-reviewed journal for publication. We hope the results of this network meta-analysis will help clinicians and patients to select an

optimal laryngeal mask.

Author contributions JTL and KHY planned and designed the research. JTL, XNX, MYL, RJC, and KHY tested the feasibility of the study. JTL and KHY provided methodological advice, polished and revised the manuscript. JTL, XNX, and KHY wrote the manuscript. All authors approved the final version of the manuscript.

Competing interests The authors have no conflicts of interest to disclose.

Patient consent Patient consent is not required since this is a meta-analysis based on published studies.

Funding: None.

Reference

[1] Brain AI. The laryngeal mask—a new concept in airway management. Br J Anaesth 1983;55:801-5.

[2] Brimacombe J. The advantages of the LMA over the tracheal tube or facemask: a meta-analysis. Can J Anaesth 1995;42:1017-23

[3] Kattwinkel J, Perlman JM, Aziz K, et al. American Heart Association. Neonatal resuscitation: 2010 American Heart Association Guidelines for Cardiopulmonary

Resuscitation and Emergency Cardiovascular Care. Pediatrics 2010;26:e1400-13.

[4] Trevisanuto D. Laryngeal mask airway for the interhospital transport of neonates. Pediatrics 2005;115:e109-11.

[5] Galderisi A, De Bernardo G, Lorenzon E, et al. I-gel: a new supraglottic device for effective resuscitation of a very low birthweight infant with Cornelia de Lange syndrome. BMJ Case Rep 2015;2015:1-2.

[6] Trevisanuto D, Parotto M, Doglioni N, et al. The supreme Laryngeal Mask Airway (LMA): a new neonatal supraglottic device: comparison with Classic and ProSeal LMA in a manikin. Resuscitation 2012;83:97-100.

[7] Choi GJ, Kang H, Baek CW, et al. A systematic review and meta-analysis of the i-gel® vs laryngeal mask airway in children. Anaesthesia 2014;69:1258-65.

[8] de Montblanc J, Ruscio L, Mazoit JX, et al. A systematic review and meta-analysis of the i-gel® vs laryngeal mask airway in adults. Anaesthesia 2014;69:1151-62.

[9] Park SK, Choi GJ, Choi YS, et al. Comparison of the i-gel and the laryngeal mask airway proseal during general anesthesia: a systematic review and meta-analysis. PLoS One 2015;10:e0119469.

[10] Shin HW, Yoo HN, Bae GE, et al. Comparison of oropharyngeal leak pressure and clinical performance of LMA ProSeal™ and i-gel® in adults: Meta-analysis and systematic review. J Int Med Res 2016;44:405-18.

[11] Li L, Catalá-López F, Alonso-Arroyo A, et al. The global research collaboration of network meta-analysis: a social network analysis. PLoS One 2016;11:e0163239.

[12] Li L, Tian J, Tian H, et al. Network meta-analyses could be improved by searching more

sources and by involving a librarian. J Clin Epidemiol 2014;67:1001-7.

[13] Ge L, Tian JH, Li YN, et al. Association between prospective registration and overall reporting and methodological quality of systematic reviews: a meta-epidemiological study. J Clin Epidemiol 2018;93:45-55.

[14] Tian JH, Zhang J, Ge L, et al. The methodological and reporting quality of systematic reviews from China and the USA are similar. J Clin Epidemiol 2017;85:50-8.

[15] Yao L, Sun R, Chen YL, et al. The quality of evidence in Chinese meta-analyses needs to be improved. J Clin Epidemiol 2016;74:73-9.

[16] Li XX, Zheng Y, Chen YL, et al. The reporting characteristics and methodological quality of Cochrane reviews about health policy research. Health Policy 2015;119:503-10.

[17] Bafeta A, Trinquart L, Seror R, et al. Reporting of results from network meta-analyses: methodological systematic review. BMJ 2014;348:g1741.

[18] Turner RM, Davey J, Clarke MJ, et al. Predicting the extent of heterogeneity in meta‐analysis, using empirical data from the Cochrane Database of Systematic Reviews. Int J Epidemiol 2012;41:818-27.

[19] Hutton B, Salanti G, Caldwell DM, et al. The PRISMA extension statement for reporting of systematic reviews incorporating network meta-analyses of health care interventions: checklist and explanations. Ann Intern Med 2015;11:777-84.

[20] Yan P, Yao L, Li H, et al. The methodological quality of robotic surgical meta-analyses needed to be improved: a cross-sectional study. J Clin Epidemiol 2019;109:20-9.

[21] Lawn JE, Cousens S, Zupan J, et al. 4 million neonatal deaths: when? Where? Why? Lancet 2005;365:891-900.

[22] Lunn DJ, Thomas A, Best N, et al. WinBUGS-A Bayesian modeling framework: concepts, structure, and extensibility. Stat Comput 2000;10:325-37.

[23] Lu G, Ades AE. Combination of direct and indirect evidence in mixed treatment comparisons. Stat Med 2004;23:3105-24.

[24] Salanti G. Indirect and mixed-treatment comparison, network, or multiple ‐ treatments meta ‐ analysis: many names, many benefits, many concerns for the next generation evidence synthesis tool. Res Synth Methods 2012;3:80-97.

[25] Begg CB, Mazumdar M. Operating characteristics of a rank correlation test for publication bias. Biometrics 1994;50:1088.

[26] Egger M, Davey Smith G, Schneider M, et al. Bias in meta-analysis detected by a simple, graphical test. BMJ 1997;315:629-34.

[27] Balshem H, Helfand M, Schünemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. J Clin Epidemiol 2011;64:401-6.

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Reported on Page #
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	Not Applicable
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2 and 4
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	12
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	Not Applicable
Support:			
Sources	5a	Indicate sources of financial or other support for the review	12
Sponsor	5b	Provide name for the review funder and/or sponsor	12
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	12
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	3 and 4
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	4
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	5
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	5
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	7 and 8

Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	6
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	5
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	6
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	6
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	5
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	8 and 9
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	9 and 10
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	9 and 10
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	10
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	9 and 10
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	9 and 10
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	11

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

BMJ Open

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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-032691.R1
Article Type:	Protocol
Date Submitted by the Author:	27-Oct-2019
Complete List of Authors:	Liu, Jieting; Lanzhou University Second Hospital, Department of Anesthesiology Xu, Xiaonan; Lanzhou University Second Hospital, Department of Anesthesiology Li, Muyang; The Second Clinical Medical College of Lanzhou University Cai, Runjin; The Second Clinical Medical College of Lanzhou University Yang, Kehu; evidence based meidicine center, lanzhou university
Primary Subject Heading:	Anaesthesia
Secondary Subject Heading:	Anaesthesia, Paediatrics
Keywords:	Airway complications, laryngeal mask airway, i-gel, general anesthesia, child, network meta-analysis

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

Jieting Liu,[1] Xiaonan Xu,[1] Muyang Li,[2] Runjin Cai,[2] Kehu Yang,[3,4*]

[1] Department of Anesthesiology, Second Hospital of Lanzhou University, Lanzhou, China

[2] The Second Clinical Medical College of Lanzhou University, Lanzhou, China

[3] Evidence-Based Medicine Center, School of Basic Medical Sciences, Lanzhou University, Lanzhou, China

[4] Key Laboratory of Evidence-Based Medicine and Knowledge Translation of Gansu Province, Lanzhou, 730000, China

[*] **Correspondence to** Kehu Yang, Evidence-Based Medicine Centre, School of Basic Medical Sciences, Lanzhou University; Key Laboratory of Evidence-Based Medicine and Knowledge Translation of Gansu Province, No.199, Donggang West Road, Lanzhou City, 730000, Gansu Province, China. (Email: kehuyangebm2006@126.com).

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 anesthesia 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 anesthesia using a Bayesian network meta-analysis.

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 randomized controlled trials (RCTs) that reported the subtypes of laryngeal mask airway and i-gel regardless of sample size. The risk of bias assessment of the included RCTs will be conducted according to the Cochrane Handbook 5.1.0. A Bayesian NMA will be performed using WinBUGS 14. GRADE will be used to explore the quality of evidence.

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

PROSPERO registration number: CRD42019127668.

Keywords: Airway complications, laryngeal mask airway, i-gel, general anesthesia, child, network meta-analysis

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 anesthesia.
- 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.
- The results of this network meta-analysis will help clinicians and patients to select an optimal laryngeal mask.
- Our results will be limited by the number of available trials and the quality of included trials.

1. Introduction

In 1983, Brain AI has introduced the new concept in airway management-laryngeal mask, but the laryngeal mask airway (LMA) was introduced in 1988 in the United States[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 anesthesia and emergency situations in child patients. Compared to 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 anesthesia 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).

Network meta-analysis has been considered to extend conventional meta-analysis on multiple treatments for a given condition[11,12]. As we know, well-conducted systematic reviews and meta-analyses of randomized 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 visualization 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 health-care decision making has been recognized and accepted by different health technology assessments and funding agencies worldwide [18]. Therefore, we will conduct a systematic review and network meta-analysis to evaluate the airway complications of all subtypes of laryngeal mask airway and i-gel in child patients under general anesthesia.

2. Methods

The current network meta-analysis will be conducted by following the Preferred Reporting Items for network meta-analyses guidelines[19]. The protocol for this network meta-analysis has been registered on PROSPERO (International Prospective Register of Systematic Reviews). The registration number is CRD42019127668.

2.1. Eligibility criteria

2.1.1. Type of study. We will include prospective randomized controlled trials that reported the subtypes of laryngeal mask airway and i-gel regardless of the sample size.

2.1.2. Type of patients. Child patients are younger than 18 years of age under general anesthesia.

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

2.1.4. 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 inflation, 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 is available.

2.2. Data sources

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

2.3. Study selection

Two review authors will independently screen titles and abstracts of each record retrieved by EndNote X8 (Thomson Reuters (Scientific) LLC Philadelphia, PA, US). 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 predefined extraction form with detailed written instructions which will be created using Microsoft Excel 2013 (Microsoft Corp, Redmond, WA, 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 E-mail (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 number 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

2.4. 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

2.5. Risk of bias of individual studies

Two reviewers will independently use the Cochrane Handbook V.5.1.0 for systematic reviews 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 7 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.

2.6. 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 (13.0; Stata Corporation, College Station, Texas, USA). If a pair of interventions are not connected to the rest of the network, we will exclude those interventions from the network meta-analysis 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.

2.7 Statistical analysis

2.7.1 Pairwise meta-analyses. For airway complications, we will calculate the average odds ratio with the 95% confidence interval (95% CI) using the random-effects model based on the DerSimonian and Laird method adjusted by the Knapp–Hartung method[22]. We will assess statistical heterogeneity within each pairwise comparison using the I^2 statistic, and I^2 values of 25%, 50%, and 75% represent mild, moderate, and severe inconsistency, respectively[22]. We will explore sources of heterogeneity by subgroup analyses and meta-regression analyses. If clinical heterogeneity is present, the pairwise comparison will not be included in the network meta-analysis.

2.7.2 Network meta-analysis. The NMA will be performed in a Bayesian hierarchical framework using Markov Chain Monte Carlo method in WinBUGS 14 (MRC Biostatistics Unit, Cambridge University, UK)[23]. We will use the node splitting method to examine the

inconsistency for each loop between direct and indirect comparisons if a loop connecting 3 or more arms exist[24-25]. To rank the treatments according to each outcome accounting for the uncertainty in the treatment effects, we used the surface under the cumulative ranking curve (SUCRA)[26]. The absolute rank of the treatment per outcome is presented using 'Rankograms' that visually show the distribution of ranking probabilities[26]. All the result figures will be generated using STATA (13.0; Stata Corporation, College Station, Texas, USA Stata) software.

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

2.8. 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[27-28].

2.9. 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 4 levels: high level, moderate level, low level, and very low level[29].

3. Ethics and dissemination

Ethics approval and patient consent are not required as this study is a network meta-analysis based on published trials. This study will summarize and provide evidence of airway complications in the subtypes of laryngeal mask airway and i-gel in child patients under general anesthesia. The results will be submitted to a peer-reviewed journal for publication. We hope the results of this network meta-analysis will help clinicians and patients to select an optimal laryngeal mask.

Author contributions JTL and KHY planned and designed the research. JTL, XNX, MYL, RJC, and KHY tested the feasibility of the study. JTL and KHY provided methodological advice, polished and revised the manuscript. JTL, XNX, and KHY wrote the manuscript. All authors approved the final version of the manuscript.

Competing interests The authors have no conflicts of interest to disclose.

Patient consent Patient consent is not required since this is a meta-analysis based on published studies.

Patient and Public Involvement No patient involved.

Funding: None.

Reference

[1] Brain AI. The laryngeal mask—a new concept in airway management. Br J Anaesth 1983;55:801-5.

[2] Brimacombe J. The advantages of the LMA over the tracheal tube or facemask: a meta-analysis. Can J Anaesth 1995;42:1017-23

[3] Kattwinkel J, Perlman JM, Aziz K, et al. American Heart Association. Neonatal resuscitation: 2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Pediatrics 2010;26:e1400-13.

[4] Trevisanuto D. Laryngeal mask airway for the interhospital transport of neonates. Pediatrics 2005;115:e109-11.

[5] Galderisi A, De Bernardo G, Lorenzon E, et al. I-gel: a new supraglottic device for effective resuscitation of a very low birth weight infant with Cornelia de Lange syndrome. BMJ Case Rep 2015;2015:1-2.

[6] Trevisanuto D, Parotto M, Doglioni N, et al. The supreme Laryngeal Mask Airway (LMA): a new neonatal supraglottic device: comparison with Classic and ProSeal LMA in a manikin. Resuscitation 2012;83:97-100.

[7] Choi GJ, Kang H, Baek CW, et al. A systematic review and meta-analysis of the i-gel® vs

laryngeal mask airway in children. Anaesthesia 2014;69:1258-65.

[8] de Montblanc J, Ruscio L, Mazoit JX, et al. A systematic review and meta-analysis of the i-gel® vs laryngeal mask airway in adults. Anaesthesia 2014;69:1151-62.

[9] Park SK, Choi GJ, Choi YS, et al. Comparison of the i-gel and the laryngeal mask airway proseal during general anesthesia: a systematic review and meta-analysis. PLoS One 2015;10:e0119469.

[10] Shin HW, Yoo HN, Bae GE, et al. Comparison of oropharyngeal leak pressure and clinical performance of LMA ProSeal™ and i-gel® in adults: Meta-analysis and systematic review. J Int Med Res 2016;44:405-18.

[11] Gao Y, Ge L, Ma X, et al. Improvement needed in the network geometry and inconsistency of Cochrane network meta-analyses: a cross-sectional survey. J Clin Epidemiol 2019;113:214-27.

[12] Li L, Tian J, Tian H, et al. Network meta-analyses could be improved by searching more sources and by involving a librarian. J Clin Epidemiol 2014;67:1001-7.

[13] Ge L, Tian JH, Li YN, et al. Association between prospective registration and overall reporting and methodological quality of systematic reviews: a meta-epidemiological study. J Clin Epidemiol 2018;93:45-55.

[14] Tian JH, Zhang J, Ge L, et al. The methodological and reporting quality of systematic reviews from China and the USA are similar. J Clin Epidemiol 2017;85:50-8.

[15] Yao L, Sun R, Chen YL, et al. The quality of evidence in Chinese meta-analyses needs to be improved. J Clin Epidemiol 2016;74:73-9.

[16] Li XX, Zheng Y, Chen YL, et al. The reporting characteristics and methodological quality

of Cochrane reviews about health policy research. Health Policy 2015;119:503-10.

[17] Bafeta A, Trinquart L, Seror R, et al. Reporting of results from network meta-analyses: methodological systematic review. BMJ 2014;348:g1741.

[18] Bafeta A, Trinquart L, Seror R, et al. Analysis of the systematic reviews process in reports of network meta-analyses: methodological systematic review. BMJ 2013;347:f3675.

[19] Hutton B, Salanti G, Caldwell DM, et al. The PRISMA extension statement for reporting of systematic reviews incorporating network meta-analyses of health care interventions: checklist and explanations. Ann Intern Med 2015;11:777-84.

[20] Yan P, Yao L, Li H, et al. The methodological quality of robotic surgical meta-analyses needed to be improved: a cross-sectional study. J Clin Epidemiol 2019;109:20-9.

[21] Higgins JP, Altman DG, Gotzsche PC, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. BMJ (Clinical research ed) 2011;343:d5928.

[22] Collet C, Asano T, Miyazaki Y, et al. Late thrombotic events after bioresorbable scaffold implantation: a systematic review and meta-analysis of randomized clinical trials. Eur Heart J 2017;38:2559-66.

[23] Lunn DJ, Thomas A, Best N, et al. WinBUGS-A Bayesian modeling framework: concepts, structure, and extensibility. Stat Comput 2000;10:325-37.

[24] Dias S, Welton NJ, Caldwell DM, et al. Checking consistency in mixed treatment comparison meta-analysis. Statistics in Medicine 2010;29:932-44.

[25] Dias S, Welton NJ, Sutton AJ, et al. Evidence synthesis for decision making 4: inconsistency in networks of evidence based on randomized controlled trials. Medical Decision Making 2013;33:641-56.

[26] Salanti G, Ades AE, Ioannidis JP. Graphical methods and numerical summaries for presenting results from multiple-treatment meta-analysis: an overview and tutorial. J Clin Epidemiol 2011;64:163-71.

[27] Begg CB, Mazumdar M. Operating characteristics of a rank correlation test for publication bias. Biometrics 1994;50:1088.

[28] Egger M, Davey Smith G, Schneider M, et al. Bias in meta-analysis detected by a simple, graphical test. BMJ 1997;315:629-34.

[29] Puhan MA, Schünemann HJ, Murad MH, et al. A GRADE Working Group approach for rating the quality of treatment effect estimates from network meta-analysis. BMJ 2014;349:g5630.

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

Search strategy of Embase.com as follows:

#1 'laryngeal mask'/exp OR "laryngeal mask airways":ab,ti OR "laryngeal masks":ab,ti OR "aryngeal masks":ab,ti OR "arynx masks":ab,ti OR "laryngeal mask airway":ab,ti OR "laryngeal mask":ab,ti OR "aryngeal mask":ab,ti OR "arynx mask":ab,ti OR LMA:ab,ti

#2 i-gel:ab,ti OR igel:ab,ti OR "i gel":ab,ti

#3 #1 OR #2

#4 'multicenter study (topic)'/exp OR 'phase 2 clinical trial (topic)'/exp OR 'phase 3 clinical trial (topic)'/exp OR 'phase 4 clinical trial (topic)'/exp OR 'controlled clinical trial (topic)'/exp OR 'randomized controlled trial (topic)'/exp OR 'single blind procedure'/exp OR 'double blind procedure'/exp

#5 random*:ab,ti OR blind*:ab,ti OR singleblind*:ab,ti OR doubleblind*:ab,ti OR trebleblind*:ab,ti OR tripleblind*:ab,ti

#6 #4 OR #5

#7 #3 AND #6

Search strategy of Cochrane library as follows:

#1 MeSH descriptor: [laryngeal masks] explode all trees

#2 ("laryngeal mask airways"):ti,ab,kw OR ("laryngeal masks"):ti,ab,kw OR ("aryngeal masks"):ti,ab,kw OR ("arynx masks"):ti,ab,kw OR ("laryngeal mask airway"):ti,ab,kw OR ("laryngeal mask"):ti,ab,kw OR ("aryngeal mask"):ti,ab,kw OR ("arynx mask"):ti,ab,kw OR (LMA):ti,ab,kw

#3 (i-gel):ti,ab,kw OR (igel):ti,ab,kw OR ("i gel"):ti,ab,kw

#4 #1 OR #2 OR #3

Search strategy of Web of Science as follows:

#1 TS=("laryngeal mask airways" OR "laryngeal masks" OR "aryngeal masks" OR "arynx masks" OR "laryngeal mask airway" OR "laryngeal mask" OR "aryngeal mask" OR "arynx mask" OR LMA)
#2 TS=(i-gel OR igel OR "i gel")
#3 #1 OR #2
#4 TS=(random* OR blind* OR singleblind* OR doubleblind* OR trebleblind* OR tripleblind*)
#5 #3 AND #4

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Reported on Page #
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	Not Applicable
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2 and 4
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	12
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	Not Applicable
Support:			
Sources	5a	Indicate sources of financial or other support for the review	12
Sponsor	5b	Provide name for the review funder and/or sponsor	12
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	12
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	3 and 4
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	4
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	5
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	5
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	7 and 8

Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	6
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	5
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	6
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	6
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	5
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	8 and 9
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	9 and 10
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	9 and 10
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	10
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	9 and 10
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	9 and 10
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	11

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

BMJ Open

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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-032691.R2
Article Type:	Protocol
Date Submitted by the Author:	29-Nov-2019
Complete List of Authors:	Liu, Jieting; Lanzhou University Second Hospital, Department of Anesthesiology Xu, Xiaonan; Lanzhou University Second Hospital, Department of Anesthesiology Li, Muyang; The Second Clinical Medical College of Lanzhou University Cai, Runjin; The Second Clinical Medical College of Lanzhou University Yang, Kehu; evidence based meidicine center, lanzhou university
Primary Subject Heading:	Anaesthesia
Secondary Subject Heading:	Anaesthesia, Paediatrics
Keywords:	Airway complications, laryngeal mask airway, i-gel, general anesthesia, child, network meta-analysis

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

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

Jieting Liu,[1] Xiaonan Xu,[1] Muyang Li,[2] Runjin Cai,[2] Kehu Yang,[3,4*]

[1] Department of Anesthesiology, Second Hospital of Lanzhou University, Lanzhou, China

[2] The Second Clinical Medical College of Lanzhou University, Lanzhou, China

[3] Evidence-Based Medicine Center, School of Basic Medical Sciences, Lanzhou University, Lanzhou, China

[4] Key Laboratory of Evidence-Based Medicine and Knowledge Translation of Gansu Province, Lanzhou, 730000, China

[*] **Correspondence to** Kehu Yang, Evidence-Based Medicine Centre, School of Basic Medical Sciences, Lanzhou University; Key Laboratory of Evidence-Based Medicine and Knowledge Translation of Gansu Province, No.199, Donggang West Road, Lanzhou City, 730000, Gansu Province, China. (Email: kehuyangebm2006@126.com).

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 anesthesia 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 anesthesia using a Bayesian network meta-analysis.

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 randomized controlled trials (RCTs) that reported the subtypes of laryngeal mask airway and i-gel regardless of sample size. The risk of bias assessment of the included RCTs will be conducted according to the Cochrane Handbook 5.1.0. A Bayesian NMA will be performed using WinBUGS 1.4.3. GRADE will be used to explore the quality of evidence.

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

PROSPERO registration number: CRD42019127668.

Keywords: Airway complications, laryngeal mask airway, i-gel, general anesthesia, child, network meta-analysis

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 anesthesia.

- 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.

1. Introduction

In 1983, Brain AI has introduced the new concept in airway management-laryngeal mask, but the laryngeal mask airway (LMA) was introduced in 1988 in the United States[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 anesthesia and emergency situations in child patients. Compared to 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 anesthesia 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).

Network meta-analysis has been considered to extend conventional meta-analysis on multiple treatments for a given condition[11,12]. As we know, well-conducted systematic reviews and meta-analyses of randomized 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 visualization 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 health-care decision making has been recognized and accepted by different health technology assessments and funding agencies worldwide [18]. Therefore, we will conduct a systematic review and network meta-analysis to evaluate the airway complications of all subtypes of laryngeal mask airway and i-gel in child patients under general anesthesia.

2. Methods

The current network meta-analysis will be conducted by following the Preferred Reporting Items for network meta-analyses guidelines[19]. The protocol for this network meta-analysis has been registered on PROSPERO (International Prospective Register of Systematic Reviews).

The registration number is CRD42019127668.

2.1. Eligibility criteria

2.1.1. Type of study. We will include prospective randomized controlled trials that reported the subtypes of laryngeal mask airway and i-gel regardless of the sample size.

2.1.2. Type of patients. Child patients are younger than 18 years of age under general anesthesia.

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

2.1.4. 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 is available.

2.2. Data sources

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

2.3. Study selection

Two review authors will independently screen titles and abstracts of each record retrieved by EndNote X8 (Thomson Reuters (Scientific) LLC Philadelphia, PA, US). 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 Corp, Redmond, WA, 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 E-mail (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 number 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

2.4. 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

2.5. Risk of bias of individual studies

Two reviewers will independently use the Cochrane Handbook V.5.1.0 for systematic reviews 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 7 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.

2.6. 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 (13.0; Stata Corporation, College Station, Texas, USA). If a pair of interventions are not connected to the rest of the network, we will exclude those interventions from the network meta-analysis 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.

2.7 Statistical analysis

2.7.1 Pairwise meta-analyses. For airway complications, we will calculate the average odds ratio and the 95% confidence interval (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].

2.7.2 Network meta-analysis. The NMA will be performed in a Bayesian hierarchical framework using Markov Chain Monte Carlo method in WinBUGS 1.4.3 (MRC Biostatistics Unit, Cambridge University, UK)[25]. If the network contains any loops connecting 3 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 (SUCRA)[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 (13.0; Stata Corporation, College Station, Texas, USA Stata) software.

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

2.8. 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].

2.9. 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 4 levels: high level, moderate level, low level, and very low level[31].

3. Patient and public involvement

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

4. Ethics and dissemination

Ethics approval and patient consent are not required as this study is a network meta-analysis based on published trials. This study will summarize and provide evidence of airway complications in the subtypes of laryngeal mask airway and i-gel in child patients under general anesthesia. The results will be submitted to a peer-reviewed journal for publication. We hope the results of this network meta-analysis will help clinicians and patients to select an optimal laryngeal mask.

Contributions JTL and KHY planned and designed the research. JTL, XNX, MYL, RJC, and KHY tested the feasibility of the study. JTL and KHY provided methodological advice, polished and revised the manuscript. JTL, XNX, and KHY wrote the manuscript. All authors approved the final version of the manuscript.

Funding: None.

Competing interests The authors have no conflicts of interest to disclose.

Patient consent for publication Not required.

Reference

[1] Brain AI. The laryngeal mask—a new concept in airway management. Br J Anaesth 1983;55:801-5.

[2] Brimacombe J. The advantages of the LMA over the tracheal tube or facemask: a meta-analysis. Can J Anaesth 1995;42:1017-23

[3] Kattwinkel J, Perlman JM, Aziz K, et al. American Heart Association. Neonatal resuscitation: 2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Pediatrics 2010;26:e1400-13.

[4] Trevisanuto D. Laryngeal mask airway for the interhospital transport of neonates. Pediatrics 2005;115:e109-11.

[5] Galderisi A, De Bernardo G, Lorenzon E, et al. I-gel: a new supraglottic device for effective resuscitation of a very low birth weight infant with Cornelia de Lange syndrome. BMJ Case Rep 2015;2015:1-2.

[6] Trevisanuto D, Parotto M, Doglioni N, et al. The supreme Laryngeal Mask Airway (LMA): a new neonatal supraglottic device: comparison with Classic and ProSeal LMA in a

manikin. Resuscitation 2012;83:97-100.

[7] Choi GJ, Kang H, Baek CW, et al. A systematic review and meta-analysis of the i-gel® vs laryngeal mask airway in children. Anaesthesia 2014;69:1258-65.

[8] de Montblanc J, Ruscio L, Mazoit JX, et al. A systematic review and meta-analysis of the i-gel® vs laryngeal mask airway in adults. Anaesthesia 2014;69:1151-62.

[9] Park SK, Choi GJ, Choi YS, et al. Comparison of the i-gel and the laryngeal mask airway proseal during general anesthesia: a systematic review and meta-analysis. PLoS One 2015;10:e0119469.

[10] Shin HW, Yoo HN, Bae GE, et al. Comparison of oropharyngeal leak pressure and clinical performance of LMA ProSeal™ and i-gel® in adults: Meta-analysis and systematic review. J Int Med Res 2016;44:405-18.

[11] Gao Y, Ge L, Ma X, et al. Improvement needed in the network geometry and inconsistency of Cochrane network meta-analyses: a cross-sectional survey. J Clin Epidemiol 2019;113:214-27.

[12] Li L, Tian J, Tian H, et al. Network meta-analyses could be improved by searching more sources and by involving a librarian. J Clin Epidemiol 2014;67:1001-7.

[13] Ge L, Tian JH, Li YN, et al. Association between prospective registration and overall reporting and methodological quality of systematic reviews: a meta-epidemiological study. J Clin Epidemiol 2018;93:45-55.

[14] Tian JH, Zhang J, Ge L, et al. The methodological and reporting quality of systematic reviews from China and the USA are similar. J Clin Epidemiol 2017;85:50-8.

[15] Gao Y, Li J, Ma X, et al. The value of four imaging modalities in diagnosing lymph node

involvement in rectal cancer: an overview and adjusted indirect comparison. Clin Exp Med. 2019;19:225-34.

[16] Gao Y, Cai Y, Yang K, et al. Methodological and reporting quality in non-Cochrane systematic review updates could be improved: a comparative study. Journal of clinical epidemiology. 2019; published online Nov 20. doi: 10.1016/j.jclinepi.2019.11.012.

[17] Bafeta A, Trinquart L, Seror R, et al. Reporting of results from network meta-analyses: methodological systematic review. BMJ 2014;348:g1741.

[18] Bafeta A, Trinquart L, Seror R, et al. Analysis of the systematic reviews process in reports of network meta-analyses: methodological systematic review. BMJ 2013;347:f3675.

[19] Hutton B, Salanti G, Caldwell DM, et al. The PRISMA extension statement for reporting of systematic reviews incorporating network meta-analyses of health care interventions: checklist and explanations. Ann Intern Med 2015;11:777-84.

[20] Yan P, Yao L, Li H, et al. The methodological quality of robotic surgical meta-analyses needed to be improved: a cross-sectional study. J Clin Epidemiol 2019;109:20-9.

[21] Higgins JP, Altman DG, Gotzsche PC, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. BMJ (Clinical research ed) 2011;343:d5928.

[22] Chang BH, Hoaglin DC. Meta-analysis of odds ratios: current good practices. Medical Care 2017;55:328-35.

[23] Hoaglin DC. Misunderstandings about Q and 'Cochran's Q test' in meta-analysis. Stat Med 2016;35:485-95.

[24] Hoaglin DC. Practical challenges of I2 as a measure of heterogeneity. Res Synth Methods 2017;8:254.

[25] Lunn DJ, Thomas A, Best N, et al. WinBUGS-A Bayesian modeling framework: concepts, structure, and extensibility. Stat Comput 2000;10:325-37.

[26] Dias S, Welton NJ, Caldwell DM, et al. Checking consistency in mixed treatment comparison meta-analysis. Statistics in Medicine 2010;29:932-44.

[27] Dias S, Welton NJ, Sutton AJ, et al. Evidence synthesis for decision making 4: inconsistency in networks of evidence based on randomized controlled trials. Medical Decision Making 2013;33:641-56.

[28] Salanti G, Ades AE, Ioannidis JP. Graphical methods and numerical summaries for presenting results from multiple-treatment meta-analysis: an overview and tutorial. J Clin Epidemiol 2011;64:163-71.

[29] Begg CB, Mazumdar M. Operating characteristics of a rank correlation test for publication bias. Biometrics 1994;50:1088.

[30] Egger M, Davey Smith G, Schneider M, et al. Bias in meta-analysis detected by a simple, graphical test. BMJ 1997;315:629-34.

[31] Puhan MA, Schünemann HJ, Murad MH, et al. A GRADE Working Group approach for rating the quality of treatment effect estimates from network meta-analysis. BMJ 2014;349:g5630.

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

Search strategy of Embase.com as follows:

#1 'laryngeal mask'/exp OR "laryngeal mask airways":ab,ti OR "laryngeal masks":ab,ti OR "aryngeal masks":ab,ti OR "arynx masks":ab,ti OR "laryngeal mask airway":ab,ti OR "laryngeal mask":ab,ti OR "aryngeal mask":ab,ti OR "arynx mask":ab,ti OR LMA:ab,ti

#2 i-gel:ab,ti OR igel:ab,ti OR "i gel":ab,ti

#3 #1 OR #2

#4 'multicenter study (topic)'/exp OR 'phase 2 clinical trial (topic)'/exp OR 'phase 3 clinical trial (topic)'/exp OR 'phase 4 clinical trial (topic)'/exp OR 'controlled clinical trial (topic)'/exp OR 'randomized controlled trial (topic)'/exp OR 'single blind procedure'/exp OR 'double blind procedure'/exp

#5 random*:ab,ti OR blind*:ab,ti OR singleblind*:ab,ti OR doubleblind*:ab,ti OR trebleblind*:ab,ti OR tripleblind*:ab,ti

#6 #4 OR #5

#7 #3 AND #6

Search strategy of Cochrane library as follows:

#1 MeSH descriptor: [laryngeal masks] explode all trees

#2 ("laryngeal mask airways"):ti,ab,kw OR ("laryngeal masks"):ti,ab,kw OR ("aryngeal masks"):ti,ab,kw OR ("arynx masks"):ti,ab,kw OR ("laryngeal mask airway"):ti,ab,kw OR ("laryngeal mask"):ti,ab,kw OR ("aryngeal mask"):ti,ab,kw OR ("arynx mask"):ti,ab,kw OR (LMA):ti,ab,kw

#3 (i-gel):ti,ab,kw OR (igel):ti,ab,kw OR ("i gel"):ti,ab,kw

#4 #1 OR #2 OR #3

Search strategy of Web of Science as follows:

#1 TS=("laryngeal mask airways" OR "laryngeal masks" OR "aryngeal masks" OR "arynx masks" OR "laryngeal mask airway" OR "laryngeal mask" OR "aryngeal mask" OR "arynx mask" OR LMA)
#2 TS=(i-gel OR igel OR "i gel")
#3 #1 OR #2
#4 TS=(random* OR blind* OR singleblind* OR doubleblind* OR trebleblind* OR tripleblind*)
#5 #3 AND #4

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Reported on Page #
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	Not Applicable
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2 and 4
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	11
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	Not Applicable
Support:			
Sources	5a	Indicate sources of financial or other support for the review	11
Sponsor	5b	Provide name for the review funder and/or sponsor	11
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	11
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	3 and 4
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	4
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	5
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	5
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	7 and 8

Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	6
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	6
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	6
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	6
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	5
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	8
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	9 and 10
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	9 and 10
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	10
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	9 and 10
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	9 and 10
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	11

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.