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# Prewarming non-inflatable cuff laryngeal mask for mechanical ventilation
## A systematic review and meta-analysis with trial sequential analysis

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**Abstract**

**Background:** Non-inflatable cuff laryngeal masks are generally composed of thermoplastic material. The thermoplastic nature of the non-inflatable cuff will become soft and match the laryngeal anatomy better as it reaches body temperature after intubation. This meta-analysis aims to evaluate the clinical validity of prewarming non-inflatable cuff laryngeal mask before insertion.

**Methods:** We searched PubMed, Cochrane Library, Embase, Web of Science, Ovid Medline, CNKI, Wan Fang Database and VIP Database to find randomized controlled trials (RCTs) researching the clinical validity of prewarming non-inflatable cuff laryngeal mask. The retrieval time is up to June 2022. Articles published in the English and Chinese languages were considered. Quality assessment was conducted with the Cochrane Collaboration's tool and GRADE (Grading of Recommendations Assessment, Development and Evaluation) method. Subgroup analyses and trial sequential analysis (TSA) were performed to control the risk of random errors. Publication bias was assessed by funnel plots and Egger's regression test. The outcomes included sealing pressure immediately after successful ventilation, the first-attempt intubation success rate and the incidence of postoperative pharyngeal pain.

**Results:** Eight RCTs evaluating 683 patients were identified. Pooled results showed that compared to the control group, prewarming non-inflatable cuff laryngeal mask provided a higher sealing pressure immediately after successful ventilation (mean difference: 1.73 cm $H_2O$; 95% confidence interval [CI]: 0.95-2.52; $P < .0001$; $I^2 = 16$; high quality), higher first-attempt intubation success rate (risk ratio [RR]: 1.05; 95% CI: 1.01-1.09; $P = .01$; $I^2 = 26\%$; high quality, number needed to treat [NNT] = 22 [95% CI 12.5-100]) and lower incidence of postoperative pharyngeal pain (RR: 0.59, 95% CI: 0.46-0.75; $P < .0001$; $I^2 = 0$; high quality, NNT = 6 [95% CI 4.17-9.09]). The results were confirmed by TSA.

**Conclusion:** Prewarming non-inflatable cuff laryngeal mask could provide better mechanical ventilation efficiency with higher sealing pressure, a higher first-attempt intubation success rate and a lower incidence of postoperative pharyngeal pain.

**Trial registration number:** PROSPERO CRD42021245350

**Abbreviations:** CI = confidence interval, GRADE = grading of recommendations assessment, development, and evaluation, MD = standard mean difference, NNT = number needed to treat, RCTs = randomized controlled trials, RIS = required information size, RR = risk ratio, SGA = supraglottic airway, SLIPA = streamlined liner of the pharynx airway, TSA = trial sequential analysis.

**Keywords:** I-gel laryngeal mask, meta-analysis, non-inflatable cuff laryngeal mask, prewarming, streamlined liner of the pharynx airway

## 1. Introduction

Supraglottic airway (SGA) devices are increasingly used for general anesthesia as an alternative to endotracheal intubation in diverse fields of surgery.[1–3] The SGA devices can be classified into inflatable cuff laryngeal masks and non-inflatable cuff laryngeal masks according to whether they have an inflatable cuff. The I-gel laryngeal mask and streamlined liner of the pharynx airway (SLIPA) are the most common non-inflatable cuff laryngeal masks, which are generally composed of

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a thermoplastic material of medical grade.[4,5] The thermoplastic nature of the non-inflatable cuff will become soft and match the laryngeal anatomy better as it reaches body temperature after insertion.[6–8]

Sealing pressure is essential for mechanical ventilation efficiency and the prevention of aspiration.[9,10] It is an indicator of how well a supraglottic device matches the laryngeal anatomy during controlled ventilation.[11] Higher sealing pressure results from the closer contact between the cuff and the adjacent soft tissues. Previous reports have shown that a non-inflatable cuff forms a more efficient seal around the larynx with a higher sealing pressure as the temperature rises to body temperature.[7,8,12–14]

Usually, SGA devices are preserved at room temperature before insertion. Compared with preservation at room temperature, a prewarming non-inflatable cuff laryngeal mask would enable the cuff to fit the pharyngeal structure more quickly and better.[6–8] Therefore, if a prewarming laryngeal mask can provide better mechanical ventilation efficiency, it will be beneficial for intraoperative airway management. However, the melting point of thermoplastic material is above 200°C, and whether it will soften as it reaches body temperature after insertion or prewarming above the body temperature before insertion remains controversial in the clinic.[15] Although many studies have been conducted on the clinical efficacy and safety of prewarming non-inflatable cuff laryngeal masks before insertion, the practical clinical value of prewarming non-inflatable cuff laryngeal masks remains unclear.[16–18] Here, we performed a systematic review and meta-analysis with trial sequential analysis (TSA) by collecting all useful data to assess the efficacy and safety of prewarming non-inflatable cuff laryngeal masks before insertion.

## 2. Materials and Methods

### 2.1. Protocol and registration

Our research was registered and approved by the International Prospective Register of Systematic Reviews, with the registration number CRD 42021245350. This study was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.[19]

### 2.2. Search strategy

We searched English databases (PubMed, Cochrane Library, Embase, Web of Science and Ovid Medline) and electronic Chinese databases (CNKI, Wan Fang Database and VIP Database) for related articles from their inception to June 2022. Search terms included the following keywords and their Medical Subject Headings if necessary: "Prewarming," "Pre-warming," "Preheating," "Pre-heating," "Laryngeal mask," "I-gel," "I-gel laryngeal mask," "streamlined liner of the pharynx airway," and "SLIPA." Details of the search strategy are listed in the Appendix-search strategies, Supplemental Digital Content, http://links.lww.com/MD/H570. Articles published in the English and Chinese languages were considered. The references of related reviews and included studies were manually searched to obtain more appropriate relevant studies.

### 2.3. Inclusion and exclusion criteria

The inclusion criteria for studies analyzed in this meta-analysis were as follows: Participant: Adult patients (≥18 years old) underwent mechanical ventilation with non-inflatable cuff laryngeal mask; Types of interventions: Prewarming non-inflatable cuff laryngeal mask before insertion in the prewarming group and non-inflatable cuff laryngeal mask preserved at room temperature before insertion in the control group; Types of Outcomes: Sealing pressure immediately after successful ventilation as the primary outcome, first-attempt intubation

success rate and the incidence of postoperative pharyngeal pain as the secondary outcome measures; and Types of studies: Randomized control trials. Exclusion criteria included: duplicate publications; studies with incomplete, incorrect data or the research data that could not be extracted for statistical analysis.

### 2.4. Data extraction and quality evaluation

Two independent investigators (Bo Wang and Li Du) independently extracted the following data from the included trials: first author, publication year, participant characteristics (gender, age, number, types of accepted surgery), type of non-inflatable cuff laryngeal mask (I-gel laryngeal mask or SLIPA), the detailed information on the prewarming intervention (including prewarming technique, prewarming time and target temperature), the room temperature of laryngeal mask preserved and outcome parameters (sealing pressure as the primary outcome, first-attempt intubation success rate and the incidence of postoperative pharyngeal pain as the secondary outcomes). We tried to contact the corresponding authors of the literature to obtain the original data by email when the information and data were missing or incomplete in any study. In addition, we also extracted numerical data from graphs using Adobe Photoshop.[20]

Two authors (Bo Wang and Lu Zhang) evaluated the risks of bias in the selected articles according to the Cochrane's risk of bias assessment tool consisting of random sequence generation, allocation concealment, blinding of participants and physicians, blinding of outcome assessors, incomplete outcome data, selective reporting and other bias.[21,22] The risk of bias components were scored as 3 levels (low risk, unclear and high risk) in accordance with the item in the checklist.[22,23] Disagreements between investigators were resolved through arbitration of a third reviewer (Jianqiao Zheng).

In addition, the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) methodology was used to assess the quality of the evidence for each outcome by GRADE profiler version 3.6.1. All the factors that could influence the quality of evidence were evaluated carefully, including risk of bias, inconsistency, indirectness, imprecision, publication bias, large effect, plausible confounding, and dose-response gradient. The possible results for each category were "no serious limitations" (no downgrading), "serious limitations" (downgraded by 1 level), or "very serious limitations" (downgraded by 2 levels).

### 2.5. Statistical analysis

Analyses were performed using Review Manager version 5.4 (Rev Man, Cochrane Collaboration, Oxford, UK) and Stata/MP 16.0 (Stata Corp, College Station, TX). Group differences in dichotomous data were expressed as risk ratio (RR) with a 95% confidence interval (CI) and group differences in continuous data were expressed as the mean differences (MDs) with 95% CIs. Heterogeneity was quantified using the $I^2$-statistic (considering $I^2$ values as follows: low: < 25%, moderate: 25%-50%, or high: 50%).[24] When there was significant heterogeneity between the included studies ($P < .05$ or $I^2 > 50\%$), the pooled effect size was calculated using a random effects model; otherwise, a fixed effects model was used. If heterogeneity was significant, we omitted the included studies one by one from the pooled analyses in turn to find potential sources of heterogeneity. The number needed to treat to harm and its 95%CI for each dichotomous data outcome was estimated according to the Cochrane guidelines. Subgroup analyses were performed according to the type of non-inflatable cuff laryngeal mask (categorized as I-gel and SLIPA). $P < .05$ was considered statistically significant. Publication bias was assessed by a visual judgment of the funnel plots asymmetry and more objectively through

Egger's regression test.[25–27] In the case of publication bias, trim and fill analysis was performed to amend the bias. The level of $P < .05$ was considered statistically significant and indicated potential publication bias.

TSA was performed to analyze the outcomes to calculate the required information size (RIS) and correct the risks of type I error and type II error.[28,29] TSA monitoring boundaries and RIS were both quantified. For continuous outcomes, the pooled meta-analysis estimated of included trials was used to estimate the anticipated MD and variance. The risk of type I error was maintained at 2.5% with a power of 90%. It is difficult to determine a clinically significant value of the standard deviation and the variance in the sealing pressure. Therefore, the MD and variance were defined by selecting the "Low-bias Based" option in the TSA viewer.[30] For dichotomous outcomes, RIS was calculated based on the proportion of participants with an outcome in the control group and relative risk reduction of 20%. The risk of type I error was maintained at 2.5% with a power of 90%. TSA was performed using the TSA program version 0.9.5.10 Beta (http://www.ctu.dk/tsa).

## 3. Results

### 3.1. Study retrieval and selection

In total, 39 records were identified from the databases and 25 duplicates were excluded. Fourteen studies were selected for full-text review, and 6 studies were excluded for the following reasons: review (n = 2), ongoing trial (n = 2), irrelevant outcome (n = 2). Finally, 8 studies involving 683 patients were included in the meta-analysis.[6–8,16–18,31,32] A flow diagram of the literature selection process is shown in Figure 1.

### 3.2. Study characteristics

The characteristics of the included studies are shown in Table 1. The data extracted by the 2 investigators (Bo Wang and Li Du) were identical. A total of 8 studies with 641 participants were included in the meta-analysis. Of the 8 studies, 4 studies used an i-gel laryngeal mask,[6,16–18] and 4 studies used a SLIPA.[7,8,31,32] One study was performed on aged participants.[31] The prewarming intervention was performed by warmed water in 7 studies[6–8,16–18,32] and only 1 study used forced hot air for prewarming.[31] The target prewarming temperature was over 40°C (range from 40°C to 44.5°C) in 7 studies[6,7,16–18,31,32] and 37°C in 1 study.[8] In the control group, non-inflatable cuff laryngeal mask was kept at room temperature approximately 20-24°C in all studies. The main characteristics of the 8 randomized controlled trials (RCTs) are summarized in Table 1.

### 3.3. Bias risk assessment

Of the 8 RCTs, 7 described the method of generating the random sequence, 5 described the allocation concealment, and only 3 described the blinding method. All included studies were confirmed as having a low risk of incomplete outcome data, reporting and other biases. The data demonstrate that our systematic review articles are of high quality (Fig. 2).
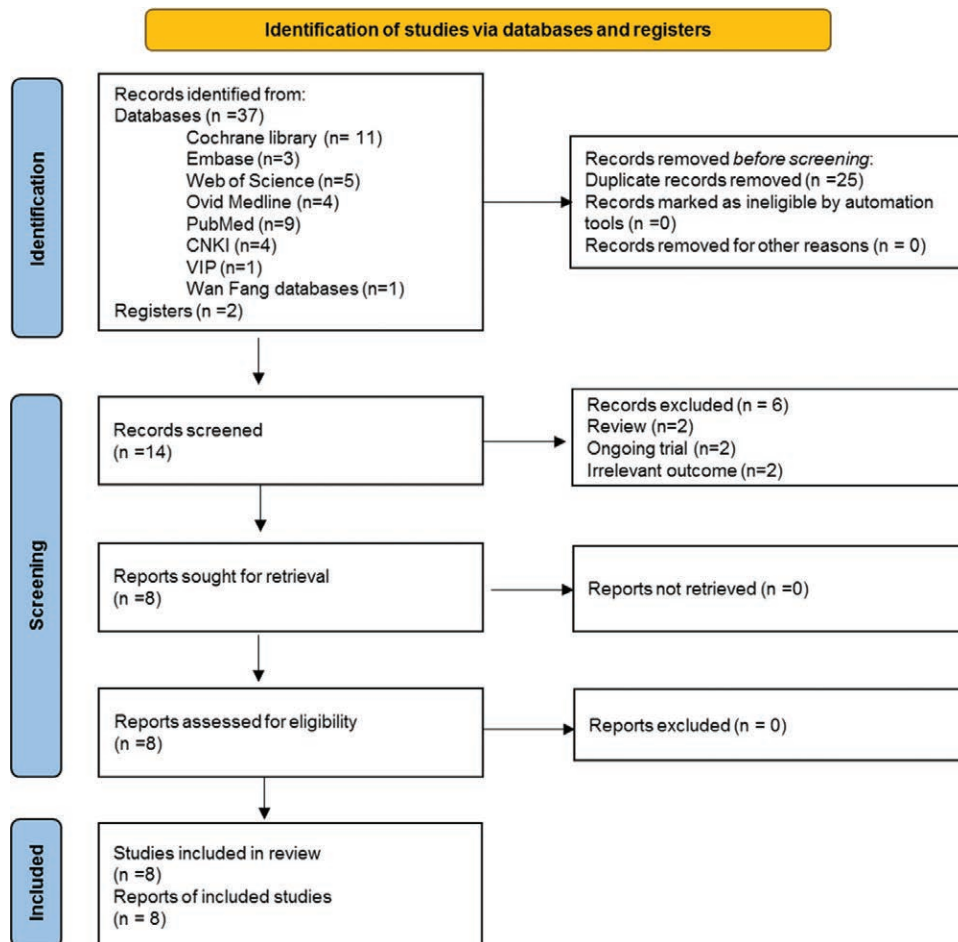


**Figure 1.** PRISMA flow diagram. PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

**Baseline characteristics of included studies.**

| Study | Yr | Participants | Type of non-inflatable cuff laryngeal mask | Group | N | Age, yr (MD ± SD) | Gender (M/F) | Intervention (Temperature before insertion) | Outcomes |
|---|---|---|---|---|---|---|---|---|---|
| Komasawa et al[6] | 2014 | Adult patients underwent general anesthesia in the supine position | I-gel | W | 34 | 60 ± 17 | 21/13 | Prewarming to 42°C in a heating cabinet with an automatic temperature control for 30 min before insertion | ①②③ |
| | | | | C | 34 | 68 ± 16 | 20/14 | Kept at room temperature (approximately 23°C) | |
| Nishiyama et al[16] | 2012 | Adult patients underwent general anesthesia in the supine position | I-gel | W | 82 | 49 ± 13 | 50/32 | Prewarming to 37°C in the warm bath with automatic temperature control for 30 min before insertion | ①② |
| | | | | C | 86 | 50 ± 14 | 45/41 | Preserved in the room temperature (approximately 20°C) | |
| Komasawa et al[17] | 2015 | Adult patients underwent general anesthesia in the supine position | I-gel | W | 37 | 56.5 ± 16.0 | 18/19 | Prewarming to 42°C in a heating cabinet with an automatic temperature control for 30 min before insertion | ①②③ |
| | | | | C | 37 | 55.0 ± 16.7 | 22/15 | Stored at room temperature (approximately 23°C) | |
| Reddy et al[18] | 2019 | Adult patients underwent general anesthesia in the supine position or lithotomy position | I-gel | W | 32 | 40.69 ± 13.40 | 24/8 | Prewarming to 40°C in a heating cabinet using a forced hot air for 15 min | ①② |
| | | | | C | 32 | 42.13 ± 12.27 | 20/12 | Kept at room temperature (approximately 23°C) | |
| Geng (1) et al[7] | 2016 | Adult patients scheduled for hysteroscopic surgery | SLIPA | W | 40 | 35.2 ± 7.4 | None | Prewarming to 42°C in the incubator for 1 h before insertion | ①②③ |
| | | | | C | 40 | 36.3 ± 7.7 | None | Kept at room temperature (approximately 24°C) | |
| Kang et al[8] | 2015 | Adult patients received general anesthesia for elective gynecologic, orthopedic, or abdominal surgery | SLIPA | W | 45 | 37.4 ± 11.6 | 18/27 | Prewarming to 37°C in warmed water, which was kept in a heating cabinet set to 37°C before insertion | ② |
| | | | | C | 44 | 41.3 ± 12.5 | 16/28 | Immersed in water at room temperature (22°C) for 15 min before insertion | |
| Jin et al[31] | 2016 | Aged patients scheduled for orthopedic surgery | SLIPA | W | 20 | 74 ± 10 | 11/9 | Prewarming in warmed water, which was kept in a heating cabinet set to 44.5°C for 20 min before insertion | ①②③ |
| | | | | C | 20 | 75 ± 10 | 12/8 | Kept at room temperature | |
| Geng (2) et al[32] | 2016 | Adult patients scheduled for hysteroscopic surgery | SLIPA | W | 50 | 35.7 ± 7.3 | None | Prewarming to 42°C in the incubator for 1 h before insertion | ①②③ |
| | | | | C | 50 | 36.2 ± 7.1 | None | Kept at room temperature (approximately 22°C-24°C) | |

C: Control group; N: Number; M: Male; F: Female; W: Prewarming group; ①: Sealing pressure immediately after successful ventilation; ②: Intubation success at first attempt; ③: Incidence of postoperative pharyngeal pain.

### 3.4. Effects of prewarming

#### 3.4.1. Primary outcome: Sealing pressure immediately after successful ventilation.
Sealing pressure was reported in 7 studies,[6,7,16–18,31,32] including 299 patients in the prewarming group and 295 in the control group. The heterogeneity of the studies was high ($I^2 = 52$ and $P = .05$). The sealing pressure of the prewarming group was significantly higher than that of the control group by the random-effect model (MD = 1.33 cm $H_2O$; 95% CI: 0.22–2.44; $P = .02$). A subgroup analysis revealed that prewarming provides a higher sealing pressure for the SLIPA (MD = 1.20 cm $H_2O$; 95% CI: 0.08–2.32; $P = .04$; low heterogeneity, $I^2 = 0$, $P = .46$), but not for the I-gel laryngeal mask (MD = 1.30 cm $H_2O$; 95% CI: -0.70 to 3.31; $P = .2$; higher heterogeneity, $I^2 = 72$, $P = .01$).

The I-gel laryngeal mask was prewarmed for only 15 minutes before insertion in 1 study, and high levels of heterogeneities disappeared ($I^2 = 16$, $P = .31$; Fig. 3A) when this study was excluded.[18] After exclusion of this study, the sealing pressure of the prewarming group was significantly higher than that of the control group (MD = 1.73 cm $H_2O$; 95% CI: 0.95–2.52; $P < .0001$; low heterogeneity, $I^2 = 16$, $P = .31$; Fig. 3A). The

results of subgroup analysis showed that prewarming provided a higher sealing pressure for the I-gel laryngeal mask (MD = 2.25 cm $H_2O$; 95% CI: 1.15–3.35; $P < .001$; low heterogeneity, $I^2 = 27$, $P = .26$) and SLIPA (MD = 1.20 cm $H_2O$; 95% CI: 0.08–2.32; $P = .04$; low heterogeneity, $I^2 = 0$, $P = .46$) (Fig. 3A). However, the results were consistent with those before excluding the given study in the fixed-effects model.

The TSA revealed that the accrued information size (n = 530) reached 62% of the estimated RIS (n = 855). The cumulative Z score crossed the trial sequential monitoring boundary (Fig. 3B). Therefore, the TSA of the pooled meta-analysis showed firm evidence for the anticipated intervention effect.

#### 3.4.2. Secondary outcomes.

##### 3.4.2.1. First-attempt intubation success rate.
The first-attempt intubation success rate was reported in all 8 studies,[6–8,16–18,31,32] which included 340 patients in the prewarming group and 343 in the control group. The heterogeneity of the studies was low ($I^2 = 26\%$, $P = .23$; Fig. 4A). The first-attempt intubation success rate of the prewarming group was significantly higher than that of the control group (RR = 1.05; 95% CI: 1.01–1.09; $P = .01$; Fig. 4A). The first-attempt intubation success rate was 96.18%
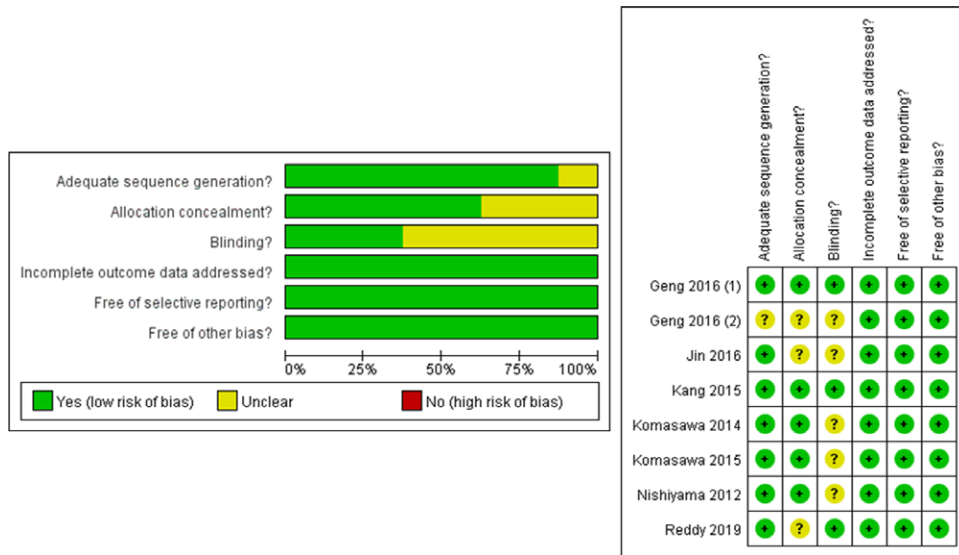
**Figure 2.** Summary of the risk of bias of the included trials.
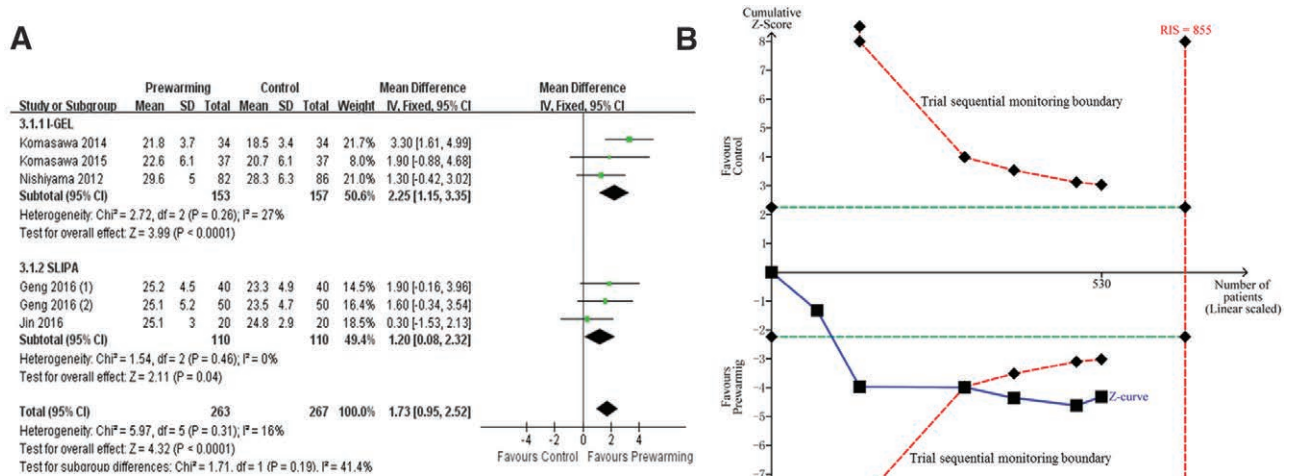


**Figure 3.** Forest plots and TSA of prewarming versus control on sealing pressure immediately after successful ventilation. (A) Forest plot for sealing pressure. (B) Mean difference and variance were defined by selecting the "Low-bias Based" option in the TSA viewer (Mean Difference 1.73; Variance 42.61). CIs = confidence intervals, RIS = required information size, TSA = trial sequential analysis.
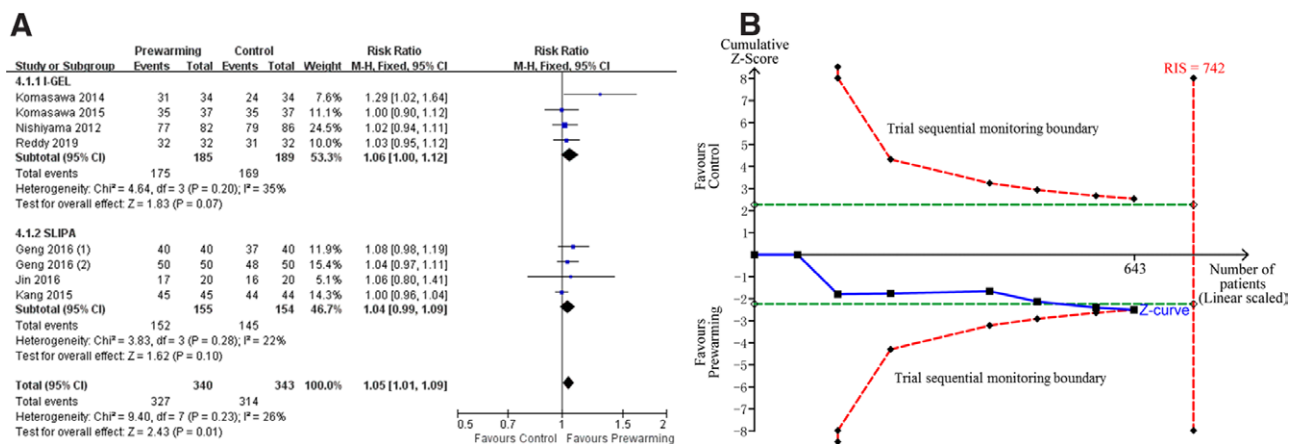


**Figure 4.** Forest plot and TSA of prewarming versus control on first-attempt intubation success rate. (A) Forest plot for the first-attempt intubation success rate. (B) TSA for a relative risk improvement of 20%. CIs = confidence intervals, RIS = required information size, TSA = trial sequential analysis.

in the prewarming group and 91.55% in the control group: absolute risk reduction 4.63%, NNT = 22; 95%CI: 12.5 to 100. A subgroup analysis revealed that the first-attempt intubation success rate was not different between the prewarming group and control groups for I-gel laryngeal mask (RR = 1.06; 95% CI: 1.00–1.12; $P = .07$; low heterogeneity, $I^2 = 35\%$, $P = .20$; Fig. 4A) and SLIPA (RR = 1.04; 95% CI: 0.99–1.09; $P = .10$; low heterogeneity, $I^2 = 22\%$, $P = .28$; Fig. 4A). For this outcome, TSA shows that the RIS is 742 patients, which is larger than the current sample (643). However, the Z-curve crossed the trial sequential monitoring boundary, which established sufficient and conclusive evidence. Thus, further trials were not required and were unlikely to alter the conclusions (Fig. 4B).

### 3.4.2.2. Incidence of postoperative pharyngeal pain.
Postoperative pharyngeal pain was reported in 5 studies,[6,7,17,31,32] including 181 patients in the prewarming group and 181 in the control group. The heterogeneity of the studies was low ($I^2 = 0$, $P = .82$; Fig. 5A). The incidence of postoperative pharyngeal pain in the prewarming group was significantly lower than that in the control group (RR = 0.59; 95% CI: 0.46–0.75; $P < .0001$; Fig. 5A). The incidence of postoperative pharyngeal pain was 23.2% in the prewarming group and 40.88% in the control group: absolute risk reduction 17.68%, NNT = 6; 95% CI: 4.17 to 9.09. A subgroup analysis revealed a significant difference in the incidence of postoperative pharyngeal pain between the prewarming and control groups for SLIPA (RR = 0.58; 95% CI: 0.46–0.74; $P < .0001$; low heterogeneity, $I^2 = 0\%$, $P = .86$) but not for I-gel laryngeal mask (RR = 1.00; 95% CI: 0.14–6.9; $P = 1.0$; low heterogeneity, $I^2 = 0\%$, $P = 1.00$) (Fig. 5A). The TSA revealed that the accrued information size (n = 368) reached only 68.1% of the estimated RIS (n = 540). However, the cumulative Z score crossed the trial sequential monitoring boundary, indicating that further studies are unlikely to alter the conclusion of the benefit of prewarming (Fig. 5B).

### 3.5. Risk of publication bias
Neither the funnel plots (Fig. 6A and C) nor Egger's regression test ($P = .888$ for sealing pressure and $P = .715$ for incidence of postoperative pharyngeal pain) showed significant publication bias for sealing pressure and the incidence of postoperative pharyngeal pain. However, the asymmetrical distribution of funnel plot tests and the result of Egger's regression test ($P = .048$) showed significant publication bias for the first-attempt intubation success rate (Fig. 6B). To reduce and adjust the publication bias in this study, trim-and-fill analysis was performed

to estimate the number of missing studies that might exist.[27] The original RR for the first-attempt intubation success rate was 1.05 (95% CI: 1.01–1.09) (Fig. 6B). After adding potentially 3 missing studies, the pooled RR was 1.04 (95% CI: 0.97–1.10) (Fig. 6D). Correction for potential publication bias did not materially alter the first-attempt intubation success rate, implying that the result was stable.

### 3.6. Quality of evidence
We assessed the level of evidence of each outcome using the GRADE criteria. The results of the GRADE analysis are presented in Table 2, and the evidence for both the primary outcome (Table 2A) and the secondary outcomes (Table 2B, 2C) was high. In the I-gel laryngeal mask subgroup, the evidence of prewarming on sealing pressure and first-attempt intubation success rate were high, while the evidence of prewarming on postoperative throat pain was low (downgraded by 2 level as the total population size is less than 300 and the CIs of the pooled RR clearly cross the line of appreciable benefit and no effect). In the SLIPA subgroup, the evidence of prewarming on first-attempt intubation success rate was high, while the evidence of prewarming on sealing pressure and postoperative throat pain was moderate (downgraded by 1 level as the total population size was less than 300).

## 4. Discussion
Sealing pressure is considered the most important determinant of the safety and efficacy of any SGA device.[33,34] It is particularly useful in the efficiency of mechanical ventilation and airway protection prevention of aspiration. Higher pharyngeal sealing pressure provides better mechanical ventilation efficiency particularly in the lithotomy position, obese patients and pneumoperitoneum.[35–39] Some authors have found that the sealing pressure of non-inflatable cuff laryngeal masks appears to improve over time, suggesting that non-inflatable cuff laryngeal masks form a more efficient seal around the larynx after warming to body temperature.[6,12–14] Prewarming non-inflatable cuff laryngeal mask to 42°C would enable the cuff to fit the pharyngeal structure more quickly than it was stored at room temperature.[6] However, Dingley et al evaluated the properties of the non-inflatable cuff laryngeal mask cuff over clinical temperature ranges and found that there was a minimal decrease in hardness and resilience with warming.[15]

In clinical practice, whether the non-inflatable cuff laryngeal mask cuff will soften as it reaches body temperature after insertion or prewarming above the body temperature before insertion
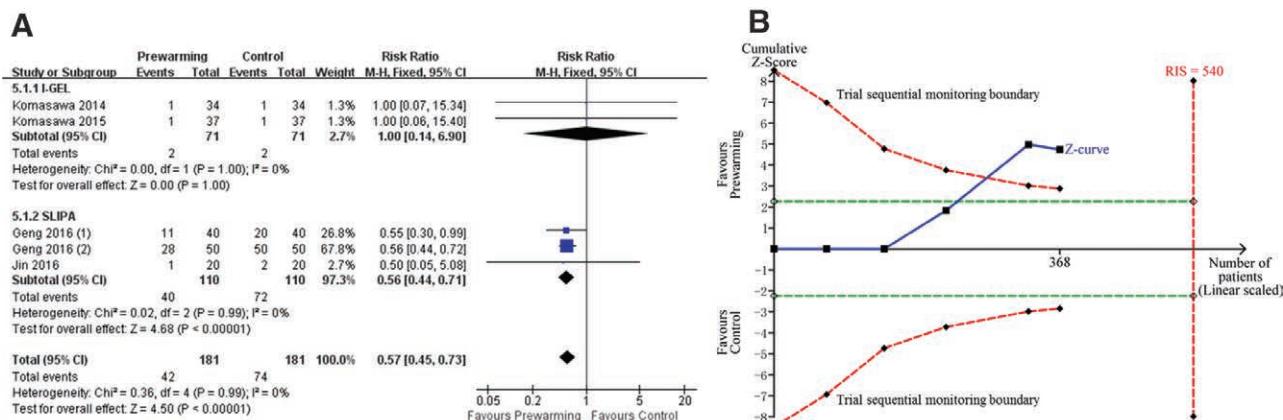


**Figure 5.** Forest plot and TSA of prewarming versus control on the incidence of postoperative pharyngeal pain. (A) Forest plot for incidence of postoperative pharyngeal pain. (B) TSA for a relative risk reduction of 20%. CIs = confidence intervals, RIS = required information size, TSA = trial sequential analysis.
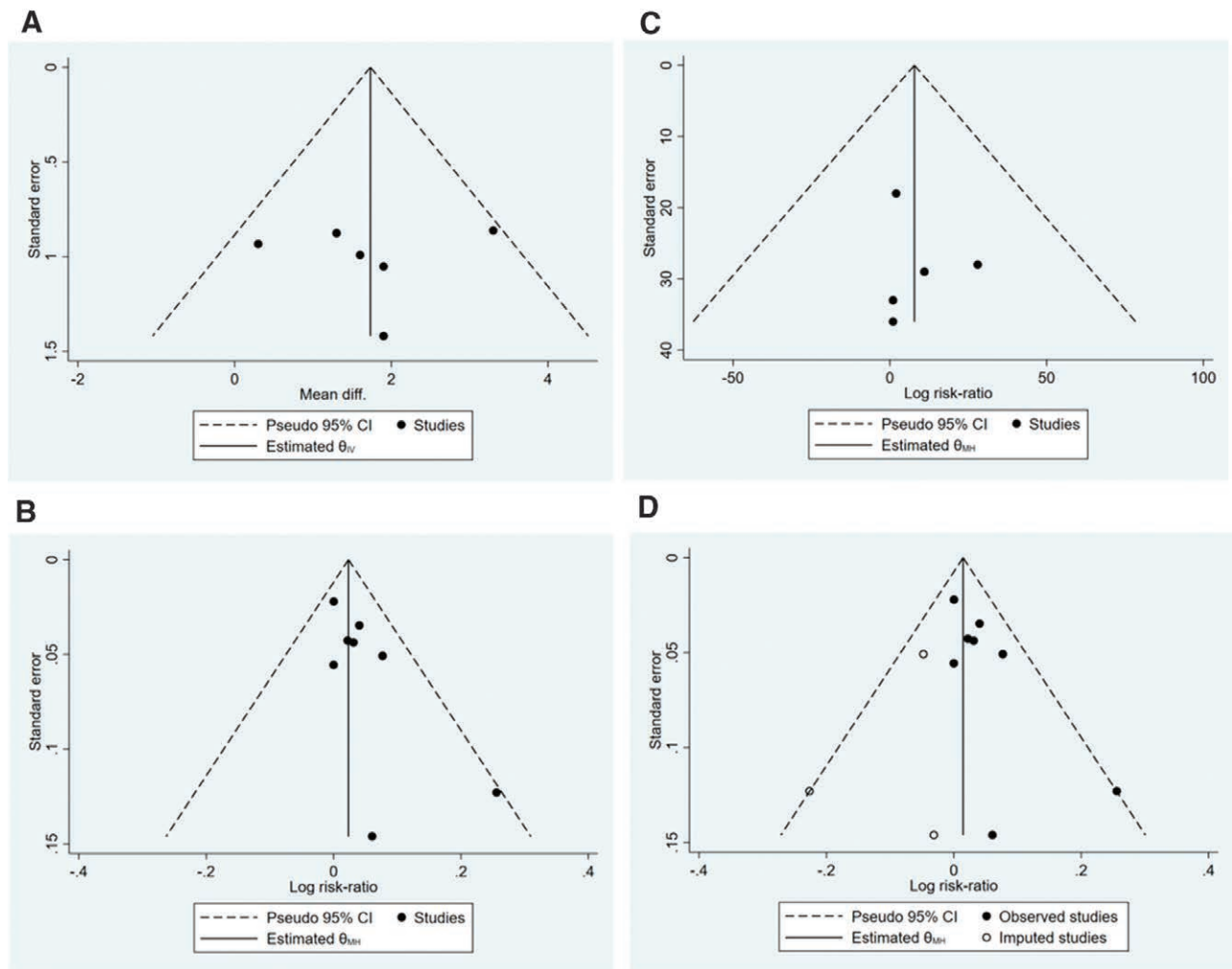
**Figure 6.** Funnel plot for publication bias of the included studies. (A) Distribution of studies included in sealing pressure. (B) Distribution of studies included in the intubation rate. (C) Distribution of studies included in the incidence of postoperative pharyngeal pain. (D) Funnel plots of the first-attempt intubation success rate after applying the trim-and-fill method. The closed dots indicate the observed studies, and the white dots indicate the missing studies imputed by the trim-and-fill method.

remains controversial. Our meta-analysis found that the sealing pressure of the prewarmed non-inflatable cuff laryngeal mask was significantly higher than it was preserved at room temperature. Martin et al revealed that all I-gel laryngeal masks have a significant temperature-dependent increase in volume and weight as well as a significant decrease in density.[40] These results may represent a new approach to explain how the prewarmed non-inflatable cuff laryngeal mask improves its sealing pressure over time after insertion.

We found that a prewarming non-inflatable laryngeal mask could enable the cuff to fit the pharyngeal structure more quickly and improve the intubation success rate, which was confirmed by TSA. Low heterogeneity ($I^2 = 26$ and $P = .23$) was revealed, which suggests that the type of non-inflatable cuff laryngeal mask does not modify the effect of prewarming. However, a smaller number of trials and participants contributed data to the I-gel laryngeal mask subgroup and SLIPA subgroup, which means that the subgroup analysis may not be able to detect subgroup differences and the advantage of prewarming may not be able displayed in the I-gel laryngeal mask subgroup and SLIPA subgroup due to the insufficient sample size.

Our results showed that the incidence of postoperative pharyngeal pain in the prewarming group was significantly lower than that in the control group, which was confirmed by TSA. Low heterogeneity ($I^2 = 0$ and $P = .82$) indicated that the type

of non-inflatable cuff laryngeal mask did not influence the effect of the prewarming procedure. As the prewarmed non-inflatable cuff laryngeal mask is softer, it probably decreases the risk for mucosal trauma and the incidence of postoperative throat pain. Subgroup analysis revealed that prewarming SLIPA provides a lower incidence of postoperative throat pain, but prewarming I-gel laryngeal mask has no advantage. Only 2 trials contributed data to the I-gel laryngeal mask subgroup, meaning that the analysis may not be able to detect the advantage of prewarming due to the insufficient sample size.

Better mechanical ventilation efficiency with higher sealing pressure, higher first-attempt intubation success rate and lower incidence of postoperative pharyngeal pain was provided by prewarming treatment, which was found in this meta-analysis and confirmed by TSA. In clinical practice, this means that prewarming non-inflatable cuff laryngeal mask could protect the airway more efficiently, decreasing the risk of regurgitation and pulmonary aspiration. In addition, it could improve the success rate of airway management related practice and reduce the risk for mucosal trauma. A relatively small number of studies were included in the subgroup analysis of I-gel laryngeal masks and SLIPA, and the clinical efficiency of prewarming could be influenced by the insufficient sample size. Due to the nature of the thermoplastic material, we still hypothesized that the prewarming I-gel laryngeal mask and SLIPA would have the same

**Table 2**

**Summary of findings table from the GRADEpro Guideline Development Tool**

### A. Primary outcome: Sealing pressure immediately after successful ventilation

**Patient or population:** Adult patients (≥18 yrs old)
**Settings:** Mechanical ventilation with non-inflatable cuff laryngeal mask
**Intervention:** Prewarming

| Outcomes | Illustrative comparative risks*(95% CI) | | Relative effect (95% CI) | No of participants (studies) | Quality of the evidence (GRADE) | Comments |
|---|---|---|---|---|---|---|
| | Assumed risk Control | Corresponding risk Sealing pressure immediately after successful ventilation | | | | |
| Sealing pressure immediately after successful ventilation | | The mean sealing pressure in the prewarming groups was **1.73 higher** (0.95 to 2.52 higher) | | 530 (6 studies) | ⊕⊕⊕⊕ **high** | |
| Sealing pressure of the I-GEL | | The mean sealing pressure in the prewarming groups was **2.25 higher** (1.15 to 3.35 higher) | | 310 (3 studies) | ⊕⊕⊕⊕ **high** | |
| Sealing pressure of the SLIPA | | The mean sealing pressure in the prewarming groups was **1.2 higher** (0.08 to 2.32 higher) | | 220 (3 studies) | ⊕⊕⊕⊖ **moderate**[1] | |

*The basis for the **assumed risk** (e.g., the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
**CI:** Confidence interval;
GRADE Working Group grades of evidence
**High quality:** Further research is very unlikely to change our confidence in the estimate of effect.
**Moderate quality:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
**Low quality:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
**Very low quality:** We are very uncertain about the estimate.
[1] Total population size is less than 300

### B. Secondary outcome: First-attempt intubation success rate

**Patient or population:** Adult patients (≥18 yrs old)
**Settings:** Mechanical ventilation with non-inflatable cuff laryngeal mask
**Intervention:** Prewarming

| Outcomes | Illustrative comparative risks* (95% CI) | | Relative effect (95% CI) | No of Participants (studies) | Quality of the evidence (GRADE) | Comments |
|---|---|---|---|---|---|---|
| | Assumed risk Control | Corresponding risk The first-attempt insertion success rate | | | | |
| The first-attempt insertion success rate | | **Study population** | **RR 1.05** (1.01 to 1.09) | 683 (8 studies) | ⊕⊕⊕⊕ **high** | |
| | 915 per 1000 | **961 per 1000** (925 to 998) | | | | |
| | | **Moderate** | | | | |
| | 936 per 1000 | **983 per 1000** (945 to 1000) | | | | |
| The first-attempt insertion success rate of I-GEL | | **Study population** | **RR 1.06** (1 to 1.12) | 374 (4 studies) | ⊕⊕⊕⊕ **high** | |
| | 894 per 1000 | **948 per 1000** (894 to 1000) | | | | |
| | | **Moderate** | | | | |
| | 932 per 1000 | **988 per 1000** (932 to 1000) | | | | |
| The first-attempt insertion success rate of SLIPA | | **Study population** | **RR 1.04** (0.99 to 1.09) | 309 (4 studies) | ⊕⊕⊕⊖ **moderate**[1] | |
| | 942 per 1000 | **979 per 1000** (932 to 1000) | | | | |
| | | **Moderate** | | | | |
| | 943 per 1000 | **981 per 1000** (934 to 1000) | | | | |

*The basis for the **assumed risk** (e.g., the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
**CI:** Confidence interval; **RR:** Risk ratio;
GRADE Working Group grades of evidence
**High quality:** Further research is very unlikely to change our confidence in the estimate of effect.
**Moderate quality:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
**Low quality:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
**Very low quality:** We are very uncertain about the estimate.
[1] Risk of bias was serious

### C. Secondary outcome: Postoperative throat pain for improvement of the laryngeal mask ventilation

**Patient or population:** Adult patients (≥18 yrs old)
**Settings:** Mechanical ventilation with non-inflatable cuff laryngeal mask

*(Continued)*

**Table 2**

*(Continued)*

| A.Primary outcome: Sealing pressure immediately after successful ventilation | | | | | | |
|---|---|---|---|---|---|---|
| **Intervention:** Prewarming **Outcomes** | | Illustrative comparative risks* (95% CI) | Relative effect (95% CI) | No of Participants (studies) | Quality of the evidence (GRADE) | Comments |
| | Assumed risk Control | Corresponding risk | | | | |
| Postoperative throat pain | | Postoperative throat pain Study population | **RR 0.57** (0.45 to 0.73) | 362 (5 studies) | ⊕⊕⊕⊖ **moderate**[1] | |
| | 409 per 1000 | 233 per 1000 | | | | |
| | | (184 to 298) Moderate | | | | |
| | 100 per 1000 | 57 per 1000 | | | | |
| | | (45 to 73) | | | | |
| Postoperative throat pain of I-GEL | | Study population | RR 1 (0.14 to 6.9) | 142 (2 studies) | ⊕⊕⊕⊖ **low**[1][2] | |
| | 28 per 1000 | 28 per 1000 | | | | |
| | | (4 to 194) Moderate | | | | |
| | 28 per 1000 | 28 per 1000 | | | | |
| | | (4 to 193) | | | | |
| Postoperative throat pain of SLIPA | | Study population | **RR 0.56** (0.44 to 0.71) | 220 (3 studies) | ⊕⊕⊕⊖ **moderate**[2] | |
| | 655 per 1000 | 367 per 1000 | | | | |
| | | (288 to 465) Moderate | | | | |
| | 500 per 1000 | 280 per 1000 | | | | |
| | | (220 to 355) | | | | |

*The basis for the **assumed risk** (e.g., the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

**CI:** Confidence interval; **RR:** Risk ratio;

GRADE Working Group grades of evidence

**High quality:** Further research is very unlikely to change our confidence in the estimate of effect.

**Moderate quality:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

**Low quality:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

**Very low quality:** We are very uncertain about the estimate.

[1] The confidence intervals of the pooled RR clearly cross the line of appreciable benefit and no effect.

[2] Total population size is less than 300.

beneficial effect on mechanical ventilation as the sample size increased. More RCT studies are needed to validate the efficacy of a prewarming different type of non-inflatable laryngeal mask, such as I-gel laryngeal mask and SLIPA in the future.

This meta-analysis has several limitations. First, the relatively small number of studies and the small sample size in the studies included in the meta-analysis are the major limitations of our study. Second, the prewarming temperature was different in the prewarming group, which may influence the result of the sealing pressure, as non-inflatable cuff laryngeal mask has a temperature-dependent volume increase. Third, the practicing anesthesiologist's familiarity with non-inflatable cuff laryngeal mask plays an important role in the result of the first intubation success rate, but most included studies were not mentioned.

## 5. Conclusion

Prewarming non-inflatable cuff laryngeal mask provides better mechanical ventilation efficiency with a higher sealing pressure, higher first-attempt intubation success rate and lower incidence of postoperative pharyngeal pain than non-inflatable cuff laryngeal masks kept at room temperature before insertion.

## Author contributions

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**Supervision:** Li Du, Lu Zhang, Jianqiao Zheng.
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**Writing – review & editing:** Lu Zhang, Jianqiao Zheng.

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