Laryngeal mask versus endotracheal intubation for pre-hospital emergency airway management: a meta-analysis of randomized control studies

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Abstract
Background: Pre-hospital emergency airway management plays an important role in pre-hospital care. Laryngeal masks are increasingly employed for the airway management of pre-hospital critical patients and have achieved promising results. Although several randomized controlled trials have reported benefits, the efficacy of laryngeal masks in pre-hospital emergency airway management compared to endotracheal intubation have not been systematically reviewed. Methods: Electronic databases (PubMed, Cochrane Library, Embase, Scopus and CNKI) were searched up to April 2019 for related randomized studies. Outcome indicators included overall intubation success rates, the success rates of the first intubation, insertion time, ventilation efficiency rates, SpO2 rise time, the blood gas index and adverse events. Two investigators selected the trials, extracted the data according to inclusion and exclusion criteria, and assessed the quality of the literature according to the Jada score. The meta-analysis was performed using stata14.0 software. Results: We included 31 human studies. Compared to endotracheal intubation, the application of laryngeal mask for pre-hospital emergencies enhanced the ventilation efficiency rates $RR=1.20$, 95% CI (1.06, 1.35), $P<0.001$, improved the success of first intubation $RR=1.29$, 95% CI (1.18, 1.40), $P<0.001$ and the patients’ blood gas index, shortened the insertion and SpO2 rise times $SMD=-3.48$, 95% CI (-4.17, -2.80), $P < 0.001$; -2.19, 95% CI (-3.06, -1.32), $P < 0.001$ and reduced the incidence of adverse events $RR=0.41$, 95% CI (0.30, 0.57, $P<0.001$. All results were stable and statistically significant.
Conclusions: Laryngeal masks could quickly and effectively improve patient ventilation in pre-hospital emergencies, highlighting its utility for clinical application.

Introduction
Pre-hospital emergency airway management is crucial in pre-hospital care and is associated with the outcomes of critical patients. Effective airway management avoids systematic hypoxia and ensures organ oxygenation to reduce mortality rates and extend the time for further medical treatments of pre-hospital critical patients. Although tracheal intubation is regarded as an effective method to maintain pulmonary ventilation, it requires a skilled operator, precise placement and rapid responses. These factors have reduced the success rates of tracheal intubation. In particular, the success rates of
tracheal intubation by non-clinical emergency personnel are generally low. In addition, tracheal intubation leads to laryngeal edema, airway injury, and other complications. Hence, some clinicians do not support tracheal intubation due to concerns over its safety and effectiveness [1]. The laryngeal mask is a novel supraglottic ventilation device that was designed based on the anatomical structure of the human pharynx, which achieves good ventilation levels without intubation. The mask can effectively reduce iatrogenic infections and pharyngeal compression injury, limiting the disruption of hemodynamics [2-3]. Recent studies reported a high efficacy of ventilation therapy when the laryngeal mask was applied to pre-hospital emergency patients. However, the majority of these studies had small sample sizes and did not adequately evaluate laryngeal mask efficacy. Hence, the effectiveness and safety of its application in pre-hospital emergency patients remains controversial [4-5]. In this study, we included randomized human studies to compare the ventilation effects of laryngeal masks and endotracheal intubation in pre-hospital emergencies, so as to provide reference for clinical practice.

Methods
This systematic review and meta-analysis were conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement to report [6].

**Data Sources and Searches**
Electronic databases (PubMed, Cochrane Library, Embase, Scopus and CNKI) were searched up to April 2019 for related randomized studies regarding laryngeal masks versus endotracheal intubation. References of the relevant studies were screened to incorporate studies that met the criteria. The retrieval strategy was adjusted according to different databases using the search terms: endotracheal intubation, laryngeal mask, and randomized controlled trial. The combination of mesh and free words were adopted and all retrieval strategies were determined by pre-retrieval. The search strategy of was as follows: (Randomized) or randomized controlled study [Title/Abstract]) OR "Randomized Controlled Trial" [Publication Type]) AND (Laryngeal Mask [Title/Abstract] OR Mask, Laryngeal [Title/Abstract] OR Masks, Laryngeal [Title/Abstract] OR Laryngeal Mask [Title/Abstract] OR Airways, Laryngeal Mask [Title/Abstract] OR Laryngeal Mask
(Title/Abstract])) OR "Laryngeal Masks"[Mesh]) AND (Anesthesia, Endotracheal[Title/Abstract] OR Endotracheal Anesthesias[Title/Abstract] OR Intratracheal Anesthesia[Title/Abstract] OR Anesthesias, Intratracheal[Title/Abstract] OR Intratracheal Anesthesias[Title/Abstract] OR Anesthesia, Intratracheal[Title/Abstract] OR Endotracheal Anesthesia[Title/Abstract] OR endotracheal tube [Title/Abstract] OR tracheal tube [Title/Abstract]) OR "Anesthesia, Endotracheal"[Mesh]).

**Study design**

Randomization

**Inclusion criteria**

Pre-hospital emergency situations: the study group underwent any type of laryngeal mask management. The control group underwent endotracheal intubation.

**Exclusion criteria**

Non-pre-hospital emergency situations, including general anesthesia surgery, manikin studies and non-randomization were excluded.

**Outcomes**

The overall intubation success rates, the success rates of first intubation, insertion times, ventilation efficiency rates, SpO2 rise times, blood gas indexes and adverse events were recorded.

**Literature screening and data extraction**

Two investigators read the titles and abstracts of the retrieved studies and excluded those that failed to meet the inclusion criteria. Full texts were those that met the inclusion criteria to determine study compliance. References were cross-checked in accordance with the inclusion criteria. Disagreements were resolved through discussions. According to the pre-designed form, the research contents mainly included: (1) general information: title of the article, author's name, source of the publications and time of the publications; (2) the characteristics of the research: the research object, study baseline comparability, and interventions; (3) the observation index: overall intubation success rates, the success rate of the first intubation and insertion time.

**Quality assessment**

The Jada scale was used to evaluate randomized research methods, blind methods, a loss of follow-up...
and withdrawal. The score was 0 to 5, ≤ 2 points were classified as low-quality studies, and ≥ 3 points were classified as high-quality studies. An independent quality assessment of the included literature was performed by two individuals and conducted and checked. Studies with inconsistent evaluations were identified through discussions and confirmed by a third reviewer.

**Data Analysis**

Stata 14.0 statistical software was used for meta-analysis. Continuous variables were expressed as mean standard differences (m ± SD / SMD) due to non-uniform units. If an article provided only the median and interquartile range (IQR), SD values were calculated according to the Cochrane manual equation: SD = IQR/1.35 [7]. Dichotomous variables were expressed as a risk ratio (RR). The 95% feasible interval (CI) was calculated for both effect sizes. Heterogeneity analysis was performed using Chi-square (x²) tests. When P < 0.05 and I² > 50%, heterogeneity existed between the studies. If no heterogeneity was observed, the fixed effect model was used. In other cases, the random effects model was employed. Subgroup analysis was conducted to explore the source of heterogeneity, such as environment and participant identity. Descriptive analysis was used if the sources of heterogeneity were not identified. Sensitivity analysis was performed through altering the effect model. Publication bias was assessed using funnel plots and Egger’s tests to determine reliability. If bias existed, metatrim methods were performed.

**Results**

**Study characteristics and quality assessment**

According to the search strategy, a total of 996 related articles were retrieved. A total of 292 articles were excluded after duplicates were removed and 673 articles were firstly included. After reading titles, abstracts and full texts, 667 articles were excluded, of which 35 were reviews. A total of 14 reports, 532 non-pre-hospital emergency studies, 40 that did not use laryngeal masks, 36 with non-randomized data, 7 with insufficient data and 9 randomized manikin studies were excluded. Finally, 31 randomized human studies [8-38] were included. The included studies focused on cases of cardiac arrest, respiratory failure, coma and other critical illnesses, and adverse effect mainly included laryngeal edema and mucosal hemorrhage, bucking, tooth loss and aspiration. All endotracheal
intubations in the included studies were performed with direct laryngoscopes. Flow diagrams for the literature selection are shown in Figure 1. The study characteristics are shown in Table 1.

**Meta-Analysis of laryngeal mask vs endotracheal intubation**

**Ventilation efficiency rates**

Meta-analysis of 17 randomized studies [8-22, 18-20, 23 25, 27, 29-31, 33] showed that the ventilation efficiency rates of the laryngeal mask groups were higher than those of the endotracheal intubation groups [RR=1.20, 95% CI (1.06, 1.35), P<0.001] without heterogeneity (P = 0.941, $I^2 = 0\%$) (Figure 2).

**Success rate of overall intubation s and first intubation**

A total of 19 [8, 11-14, 16, 19-20, 24-28, 30-33, 35-36] and 3 randomized studies [26,32, 37] reported the success rates of first intubation and overall intubation success rates, respectively. The results suggested that the success rates of first intubation for the laryngeal mask were higher than those for endotracheal intubation [RR=1.29, 95% CI (1.18, 1.40), P<0.001] without heterogeneity (P = 0.840, $I^2 = 0\%$). However, no statistical differences in overall intubation success rates were observed [RR=1.11, 95% CI (0.88, 1.39), P<0.001] without heterogeneity (P = 0.979, $I^2 = 0\%$) (Figure 3).

**Insertion time and SpO$_2$ rise time**

A total of 27 [8, 11-22, 24-28, 30-38] and 3 studies [8, 11, 24] reported insertion and SpO$_2$ rise times, respectively. The results suggested that both were shorter in the laryngeal mask groups compared to endotracheal intubation [SMD=-3.48, 95% CI (-4.17, -2.80), P < 0.001; -2.19, 95% CI (-3.06, -1.32), P < 0.001] but with significant heterogeneity (P = 0.000, $I^2 = 96.8\%$; P = 0.001, $I^2 = 85.5\%$) (Figure 4).

**Blood gas index**

Three studies [10, 23, 28] reported PaCO$_2$, PaO$_2$ and pH, and 8 studies [10, 14, 16-17, 23, 28, 35, 38] reported SpO$_2$. The pooled results showed that laryngeal mask ventilation increased pH [SMD=3.74, 95% CI (0.68, 6.80), P < 0.001, $I^2 = 97.4\%$], PaO$_2$ [SMD=2.93 95% CI (1.43, 4.42), P < 0.001, $I^2 = 91.4\%$] and SpO$_2$ [SMD=1.07, 95% CI (0.11,2.04), P < 0.001, $I^2 = 95.8\%$] and lowered PaCO$_2$
[SMD=-4.03, 95% CI (-5.32, -2.73), P < 0.001, I² =83.1%] (Figure 5).

**Overall adverse events and aspiration**

Thirteen [8,11-14,19,22-25,27-29,31,34] and five studies [8,11,22,28,31] reported the incidence rates of overall adverse events and aspiration, respectively. These suggested that laryngeal mask ventilation could reduce the occurrence of adverse events compared to endotracheal intubation [RR=0.41, 95% CI (0.30, 0.57, P<0.001, I²=0]. No differences in aspiration were observed (Figure 6).

**Subgroup analysis**

Due to the existence of heterogeneity, we performed subgroup analysis on the first success rates of the first insertion and insertion time. As shown in Table 2, we failed to identify any source of heterogeneity in insertion times across the included studies.

**Sensitivity analysis and publication bias**

The results of sensitivity analysis and publication bias are shown in Table 3. Funnel plots of included studies are shown in Figure 6. Sensitive analysis suggested that all the results were stable. Egger's tests showed the presence of publication bias in the ventilation efficiency rates and insertion times, but metatrim suggested that the bias had no influence on the final results.

**Discussion**

To our knowledge, this is the first systematic review and meta-analysis to compare the clinical effects of laryngeal mask placement and endotracheal intubation for pre-hospital emergencies. Our study showed that the overall effects of the laryngeal mask ventilation were superior to endotracheal intubation. Sensitivity analysis and publication bias tests also suggested that the results were stable and reliable.

The clinical application of the laryngeal mask for pre-hospital emergencies has unique advantages including its ease of use and the ability to rapidly maintain the airways. Even when the position of the laryngeal mask was not ideal, it can maintain airway patency [39]. A secondly advantage is that no laryngoscopes are needed. Compared to endotracheal intubation, it is easy for beginners to insert the laryngeal mask and the success rates are relatively high [40]. Thirdly, the laryngeal mask is used as a supraglottic ventilation device, which has the advantage of establishing the airways for autonomous
ventilation and ventilation control, thus avoiding mucosal damage in the trachea. Ventilation management through endotracheal intubation is not satisfactory. Cobas et al [41] reported that the failure rates of non-anesthesiologists for endotracheal intubation can be as high as 31%. Even with experienced clinicians, the misalignment rates were as high as 17.4%, of which the esophageal insertion rates were 6.7% [42]. This can be fatal for comatose patients.

Our meta-analysis showed that the success rates of first intubation in the laryngeal mask group were significantly higher than the control group, and the time taken for laryngeal mask placement was significantly shorter. These results indicate that the laryngeal mask had improved success rates for first intubation. Unlike endotracheal intubation, the use of a laryngeal mask does not involve glottis exposure, is easy to operate, and easy to master. Furthermore, its shorter placement times are beneficial to the early recovery of the patient’s ventilator function. Hypoxia in the brain tissue for more than 5 minutes can lead to irreversible brain damage; thus, establishing airway ventilation as early as possible is key to successful cardiopulmonary resuscitation. Brimacombe et al [43] reported that medical staff without experience in laryngeal mask placements were more likely to insert laryngeal masks with shorter insertion times, which was similar to our subgroup analysis. The clinical medical students of the included studies had no experience in the use of laryngeal masks, and some nurses and EMT lacked systematic training. The laryngeal mask insertion time was however shorter than that of endotracheal intubation. Subgroup analyses also suggested that paramedics, anesthesiologists, nurses, and emergency physicians have shorter insertion times for laryngeal masks in both stationary and mobile environments. The success rates of first intubation and insertion time in the laryngeal mask groups were superior to the endotracheal intubation groups, further demonstrating the advantages of the laryngeal mask. The application of the laryngeal mask in pre-hospital emergency patients benefits the early recovery of tracheal ventilation, and promotes the success of cardiopulmonary resuscitation. The drawbacks include the lack of data in the included studies.

Laryngeal mask ventilation also improved the blood gas index, leading to higher levels of PaO2 and
SpO$_2$ and shorter SpO$_2$ rise times, which are important to ensure good patient prognosis.

The risk of bias in included studies was primarily in the blinding method, which could not be implemented. Due to the small sample size, we performed Egger's tests. The results showed that the small sample effect did not influence the final data outcomes. Moreover, specific information of the human studies was unknown due to random grouping.

The study had some limitations. First, the quality of the evidence in the included studies was weak. Secondly, the sources of heterogeneity for the comparison of first intubation success rates and insertion times were not clearly identified. Thirdly, we failed to study the different methods of laryngeal masks and endotracheal intubation. Moreover, the update of the laryngeal mask was rapid with standard types, intubable types, esophageal drainage types and no cuff types. The application of these different laryngeal masks in pre-hospital emergencies also requires further exploration. Finally, “in-the-field-time” is important for pre-hospital emergencies, but we failed to explore it due to insufficient data.

Conclusions
In summary, the application of laryngeal mask for pre-hospital emergencies could enhance the success rates of first-pass intubation, reduce the placement time and decrease the incidence of pharyngeal edema, tooth loss or injury, and other complications compared to endotracheal intubation. Laryngeal masks are therefore a more effective ventilation device and should be employed in pre-hospital emergencies. Further high-quality randomized controlled trials are now required to further demonstrate the reliability of our conclusions.

Abbreviations
Laryngeal mask, LM; Endotracheal intubation, EI; Mean standard difference, SMD; Interquartile range, IQR; Standard difference, SD; Risk ratio, RR; Confidence interval, CI.

Declarations
Ethics approval and consent to participate
Not applicable.

Consent for publication
Not applicable.
Availability of data and materials

All data generated or analyzed during this study are included in this published article.

Competing interests

There are no competing interests for publication of this paper.

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Authors’ contributions

JB. C and H. L had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. JB. C and MD. D conceived and designed the study; YX. S, X. Z, M. L, WG. L and AS. H led the acquisition, analysis, or interpretation of data; H. L and MD. D drafted the manuscript, YL. Z and SH. Y, checked this work again. All authors read and approved the final manuscript.

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**Table 1. Characteristics of included studies**

| Author, year | Country | LMA(n) | ET(n) | Outcomes | Jada scores |
|--------------|---------|--------|-------|----------|-------------|
| Y Ding, 2016 | China   | 40     | 40    | B, C, D, E | 4           |
| JC Gou, 2017 | China   | 40     | 40    | D        | 4           |
| J Gao, 2015  | China   | 41     | 41    | D, F, G, H, I | 4        |
| XM Huang, 2016 | China | 40     | 40    | B, C, D, E | 4           |
| PL Li, 2018  | China   | 47     | 47    | B, C, D  | 4           |
| JC Gou, 2017 | China   | 34     | 34    | B, C, D  | 4           |
| P Long, 2018 | China   | 47     | 45    | B, C, D, I | 4          |
| JJ Lu, 2012  | China   | 41     | 50    | C        | 5           |
| G Qin, 2017  | China   | 27     | 27    | B, C, I  | 5           |
| GJ Qiu, 2018 | China   | 15     | 15    | C, I     | 4           |
| DZ Shi, 2018 | China   | 90     | 90    | C, D     | 5           |
| DJ Sun, 2017 | China   | 30     | 30    | B, C, D  | 4           |
| H Tang, 2018 | China   | 20     | 20    | B, C, D  | 4           |
| XM Tang, 2017 | China | 82     | 100   | C        | 4           |
| XQ Tu, 2018  | China   | 45     | 45    | C        | 4           |
| Q Wang, 2017 | China   | 20     | 20    | D, F, G, H, I | 4        |
| H Yan, 2017  | China   | 35     | 35    | B, C, E  | 4           |
| YZ Yuan, 2017 | China | 30     | 32    | B, C, D  | 4           |
| X Huang, 2013 | China | 25     | 25    | A, B, C  | 4           |
| H Li, 2013   | China   | 99     | 84    | B, C, D  | 5           |
| J Liang, 2016 | China | 30     | 30    | B, C, F, G, H, I | 4        |
| ZM Liang, 2016 | China | 28     | 28    | D        | 4           |
| JH Sha, 2011 | China   | 35     | 30    | B, C, D  | 4           |
| Y Wu, 2014   | China   | 40     | 40    | B, C, D  | 5           |
| FF Xia, 2013 | China   | 18     | 18    | A, B, C  | 4           |
| DM Yang, 2011 | China | 28     | 28    | B, C, D  | 4           |
| Y Yang, 2016 | China   | 30     | 30    | C        | 4           |
| L Zhou, 2013 | China   | 96     | 104   | B, C, I  | 5           |
| XH Zhou, 2016 | China | 73     | 79    | B, C     | 4           |
| CD Deakin, 2005 | UK | 52     | 52    | A, C     | 5           |
| S Khosravan, 2015 | UK | 18     | 17    | C, I     | 4           |

A, overall intubation success rate; B, success rate of first intubation; C, insertion time; D, ventilation efficiency rate; E, SpO2 rise time; F, PaCO2; G, PaO2; H, pH; I, SpO2.

**Table 2. Results summary for subgroup analysis**

| Subgroup (effect size) | Number | Effect value | Heterogeneity |
|------------------------|--------|--------------|---------------|
|                        |        |              | I^2     | P     |
| **Insertion time**     |        |              |        |      |
| (mean standard difference) |    |              |        |      |
| Cause                  |        |              |        |      |
| Cardiac arrest         | 632    | -4.01 (-5.60, -2.53) | 97.2  | 0.000 |
| Respiratory failure    | 405    | -4.26 (-5.45, -3.06) | 91.0  | 0.000 |
| Coma                   | 420    | -1.96 (-2.81, -1.12) | 91.3  | 0.000 |
| Year                   |        |              |        |      |
| 50                     | 800    | -3.11 (-4.12, -2.10) | 95.8  | 0.000 |
| 50                     | 1017   | -4.19 (-5.44, -2.95) | 97.4  | 0.000 |
Table 3. Results summary for sensitive analysis after changing effect model and publication bias

(Egger's test)

| Sensitive analysis                      | Effect size | [Effect value(95%CI), P]          | Egger's test(P) |
|-----------------------------------------|-------------|----------------------------------|-----------------|
| Human studies                           |             |                                  |                 |
| Ventilation efficiency rate             | RR          | [1.18(1.04, 1.32), 0.007]        | 0.001           |
| Success rate of initial intubation      | RR          | [1.27(1.16, 1.38), 0.000]        | 0.089           |
| Insertion time                          | SMD         | [-2.46(-2.58, -2.34), 0.000]     | 0.000           |

Figures

Figure 1

Flow diagram for the literature selection.
Figure 2
Forest plot of the ventilation efficiency rates.
**Figure 3**

Forest plot of the overall intubation success rates and success rates of the first intubation.
Figure 4

Forest plot of the insertion time and SpO2 rise time.
Figure 5

Forest plot of the blood gas index.
Figure 6

Funnel plots of overall adverse events and aspiration.

Figure 7

Funnel plots of the ventilation efficiency rates (A), the success rates of first intubation (B) and insertion times (C).
Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

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