A Novel Airway Opening Device with Automatic Position Adjustment

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Abstract

Airway opening is a key technique in the implementation of airway management. Based on the airway opening theory of CPR and tracheal intubation, we developed a new device to replace manual methods to open the airway of patients and maintain airway patency automatically and accurately. This device is a novel, automatic, non-invasive, simple, multifunctional, and widely used airway opening device, which can measure three important values of angle, adjust the lifting height of the upper body of patients, place patients in an optimized position accurately, maintain airway patency, protect the cervical spine, and dynamically display the values of angle, height, working speed, and time. Moreover, the device can be used in the clinical practices of bronchoscopy, tracheal intubation, difficult intubation, and CPR, which can free the hands of health care staff, alleviate their fatigue, and compensate for the incorrect, inadequate, or ineffective operation in the manual airway opening methods. We conducted a preliminary manikin study to evaluate the effectiveness of the device in airway opening and found that the device has good efficacy on airway opening.

1. Introduction

The airway is the most important channel to maintain the normal exchange of gas inside and outside the body and is also one of the primary treatment factors during the process of rescuing critically ill patients. The first step in airway management is to open the airway, which can help health care staff maintain airway patency and perform respiratory support interventions effectively. Whether in hospital, pre-hospital first aid, or battlefield first aid, airway opening is the core content and necessary skill for medical staff to implement airway management. As we know, the manual method is often used to open the airway of patients in clinical. However, manual methods may have problems with incorrect airway opening, inadequate airway opening, or invalid airway opening. Once the operation fails, it may lead to some severe complications such as hypoxia, dyspnea, respiratory failure, and cause some irreversible injuries to the heart or brain, or even endanger the life of patients. Therefore, we developed a new device, called the “Airway Opening Device with Automatic Position Adjustment” (Patent authorized publication number: CN110279551B), to improve and reduce the above problems. The device can replace manual methods to open and maintain the patient's airway in a permanent patent state automatically, safely, noninvasively, timely, and accurately, and can be used for patients undergoing bronchoscopy, tracheal intubation, and cardiopulmonary resuscitation (CPR). The major objective of this study is to introduce the device and explore its application effects in a CPR manikin.

2. Materials And Methods

2.1 Design theory

The theoretical background of the development of the device includes CPR and tracheal intubation open airway. In CPR, the criterion of airway opening is the line between the external auditory meatus and the mandible is perpendicular to the horizontal plane. The core theory of tracheal intubation is keeping the
head and neck of patients in an optimized position, including the three-axis alignment theory (The TAAT)\(^6\), sniffing position\(^7,8\), and ramped position\(^9,10\). Bannister et al. firstly introduced the TAAT, and suggested that the best glottic view would be obtained during laryngoscopy when the three axes of mouth, pharynx and larynx overlapped in 1944\(^6\). Sniffing position is defined as the level of the head and face raised 15° and the neck flexed 35° through placing a 7 to 10 cm pillow or blanket behind their head or shoulder\(^7,8\). Generally, sniffing position is regarded as the preferred position for tracheal intubation during laryngoscopy because it can keep the three axes aligned to some extent. Ramped position is considered as a potential good position through raising the back of beds for 20° to 25° or raising the upper body and head until the line between the external auditory meatus and the sternal notch is aligned to the horizontal plane, which may facilitate tracheal intubation and ventilation\(^9,10\). Because the proper position is a decisive factor for successful airway opening\(^11\), so we designed the device based on these two reliable and feasible theories.

2.2 Compositions and materials

The device is designed as a mobile structure, including the mechanical controls and the electronic controls. The mechanical controls are composed of a head measurement and control equipment (HMCE), a head groove (HG), a neck lifting equipment (NLE), a neck brace (NB), electronic positioning adjustment equipment (EPAE), a back panel (BP), and a horizontal bottom plate (HBP). The electronic controls consist of an operation console (OC), programmable logic controller (PLC), and positioning control system (Fig. 1).

Specifically, the first part is the OC that is equipped with a liquid crystal display (LCD) touch screen, PLC, and power. The operation interface of the LCD touch screen includes the manual angle or height adjustment option, the automatic angle or height adjustment option, the auxiliary angle adjustment option, and the help option. The second part is the HMCE consists of a ring sleeve (RS), positioning reference plate (PRP), and dynamic inclinometer (DI, SDA126T-90-485, SN 01819100183, Rion-tech, Beijing, China). The RS is used to assist patients in wearing and fixing the HMCE, and the PRP and DI are used to measure the degree of an angle, called “the mandibular angle” (MA), which is formed by the line between the mandible and the external auditory meatus and the horizontal plane. Besides, another DI (SN 01819100184) is designed to measure the degree of an auxiliary angle formed by the line between the external auditory meatus and the sternal notch and the horizontal plane, but its function remains to be developed. The third part is an HG and a guide rail (GR). The GR is longitudinally parallel to the human body under the HG, enabling the HG to better support the head of patients when their position is changed. The fourth part is the NLE connected to the EPAE, which contains a support plate (SP), NB, guide post (GP), lever, and electric cylinder (EC). The NB is used to protect the cervical spine. The end face of the SP passes through the GP and slides up or down with it. One end face of the lever is below the SP and the other end face has a chute. The end face of the telescopic rod of the EC is equipped with a driving pin, which is located in the chute of the EPAE. The EPAE is controlled by EC and its functions of setting and measuring the values of angle and height are carried out by the PLC. The final part is a BP which is hinged with the SP through the bolt, so we can choose to insert the bolt to make the BP linkage with the
NLE, or remove it to align the BP with the HBP. To make the head extent and neck flex for airway opening, the NLE, BP, and EPAP will be used in combination.

The device is made of 304 stainless steel, polytetrafluoroethylene, and polyester fiber. The type of the device is YT/QD-100Z with a voltage of 220 V, a frequency of 50 Hz, and a power of 300 W. The length, width, and height of the mechanical controls and the electronic controls are 65*54*40.5 cm and 42.6*37.8*6.5 cm, respectively. And the weight of the mechanical controls and the electronic controls are 25 kg and 8 kg, respectively.

2.3 Efficacy

The main efficacy of the device is to open the airway of patients with their head extended, neck flexed, and upper body raised through adjusting the values of angle and height automatically or manually. The method of automatic adjustment is to preset parameters of the automatic angle or height adjustment option on the LCD touch screen. To adjust manually, select the manual angle or height adjustment option, and then click the up or down option. Its specific functions are as follows.

2.3.1 Measure the degree of angle

The device can measure three important values of angle through DI and software. The first angle is the MA. The second angle, named “the angle of the BP” (BPA), is formed by the line between the BP and the horizontal plane. The last angle, called “the angle of position” (PA), is generated by the line between the BP and the projection line of the end face of the MA. As the PA is associated with the MA and the BPA, we determined to set the degree of the PA as the key parameter in the process of opening the airway of patients. Based on the airway opening criterion of CPR, we defined the degrees of the PA range from 90 to 100. Besides, medical staff can preset some alternative degrees of the PA in the operation interface, such as 90 degrees, 95 degrees, or 100 degrees, to facilitate the application of the device easier and briefer.

2.3.2 Adjust height

The device can measure the distances between the lift or lower of the BP to its initial position. The relative lifting distances (RLD) of the BP range from 0 to 50 mm, and the absolute lifting distances of the BP range from 10.3 to 15.3 cm, which is calculated with the distances between the BP and the HBP plus the height of the HBP itself. The limits of the lifting distances are to avoid adverse effects and avoid hindering the implementation of other clinical practices.

2.3.3 Position accurately

The device uses the automatic tracking model of setting error values to control the deviation, so the differences between the real and preset values of these angles and heights are less than 5%. Thus, the device can open the airway accurately and reduce some airway injuries by correctly adjusting these values of angle and height. Besides, the maximum working speed of the device can reach 20 mm/s, and the maximum RLD can be reached in just 2.5 seconds. Therefore, when a clinical emergency occurs, medical staff can select the maximum working speed to shorten the time of airway opening.
2.3.4 Maintain patent airway

The device can maintain the patient’s airway in a permanent patent state, which prevents medical staff from repeating the airway opening process, saves manpower and time, and facilitates the implementation of other clinical practices.

2.3.5 Protect the cervical spine

The device can protect and support the cervical spine of patients through the NB.

2.3.6 Dynamic display

The device can dynamically monitor and display the values of angle, height, working speed, and time, which help medical staff observe, record, and adjust these important parameters.

2.4 Application methods

The operation of the device contains six steps. The first step is to start the OC to keep the device in a standby state. The second step is to help patients wear and fix the HMCE, and slowly place their head, neck, and upper body on the device. The third step is to adjust the degrees of the PA or the heights of the BP by selecting the automatic or manual option. The fourth step is that the device will automatically open the airway of patients and keep it open when the third step is finished. After this step, some clinical practices, such as tracheal intubation and bronchoscopy, will be routinely performed. When the treatment is completed, the final step is to remove the HMCE, click the reset option, and turn off the power.

2.5 Preliminary application

All experimental protocols were approved by the First Affiliated Hospital of Chongqing Medical University Institutional Review Board (No. 20205401).

All methods were carried out in accordance with relevant guidelines and regulations. This study was conducted in the Simulation Teaching Center of Clinical Skills, the First Affiliated Hospital of Chongqing Medical University, and written informed consent was obtained from 15 students in the third year of the Nursing degree.

Before the study started, all participants received standard training on the operation of the device and the one-hand bag-valve-mask (BVM) ventilation skill in the form of a lecture and teaching lasting about 15 minutes. The participants were then allowed to practice the techniques until they passed muster.

According to the basic life support (BLS) guidelines for adult CPR, participants were required to use the BVM (Adult, Tianzuo, Xiamen, China) to ventilate twice after the airway of opening a Resusci Anne® CPR manikin (Laerdal, Wappingers Falls, NY) once using the device at the degrees of the PA were 90(90° PA group), 95(95° PA group), and 100(100° PA group), respectively. Since one cycle of BLS demands implementing compressions-airway-breathes operations 5 times, so participants repeated these study procedures 5 times.
Therefore, each group of participants used the device to open the airway 5 times and then used the BVM to ventilate 10 times.

The primary outcome was the ventilation success rate of participants. Investigators recorded the number of successful ventilation using a SkillGuide electronic display (Laerdal, Wappingers Falls, NY) that is equipped in the Resusci Anne. Besides, investigators observed whether there are visible fluctuations in the Resusci Anne's chest, which is considered as a supplementary indication.

2.6 Statistical analysis

Investigators double entered all data into Excel (version 16, 2019, Microsoft, Redmond, WA), and the statistical analyses were performed using SPSS (version 25.0, IBM, Armonk, NY). Normally distributed measurement data were expressed by mean ± standard deviation (± s) while non-normally distributed statistics were displayed as the median and interquartile range (IQR) or proportions. Friedman test was used to compare the differences in the ventilation success rate between the three groups. P < 0.05 was accepted as statistical significance.

3. Results

3.1 Baseline characteristics of participants

The study enrolled 15 participants in the third year of the Nursing degree. All participants were female and had an age distribution of 21 (range, 19 ~ 22) years old.

3.2 The distribution of the angle and height values measured by the device in the three groups

All 15 participants used the device to perform 225 times airway opening of the Resusci Anne in the three groups. Thus, there were 75 values of the MA, the BPA, the PA, and the RLD in each group (Table 1).

| Group   | N  | MA         | BPA       | PA          | RLD          |
|---------|----|------------|-----------|-------------|--------------|
|         |    | (M, IQR, °)| (M, IQR, °)| (± s, °)    | (M, IQR, mm) |
| 90° PA  | 75 | 70.8 (70.1–71.6) | 12.2 (11.2–13.1) | 90.13 ± 0.33 | 14.8 (11.7–17.7) |
| 95° PA  | 75 | 71.0 (70.5–71.5) | 17.1 (16.4–17.5) | 95.18 ± 0.26 | 30.2 (28.2–31.9) |
| 100° PA | 75 | 70.9 (70.6–71.8) | 22.3 (21.3–22.7) | 100.34 ± 0.31 | 46.8 (43.9–48.3) |

M = median; IQR = interquartile range; mm = millimeter; MA = the mandibular angle; BPA = the angle of back panel; PA = the angle of position; RLD = the relative lifting distances.

3.3 Comparison of the success rate of ventilation between groups
All participants completed the study. A total of 150 ventilations were performed in each group.

Our results showed that total numbers of successful ventilation in the 90°, 95° and 100° PA group were 133, 134, and 132, respectively, and the median ventilation success rate of participants was 100% (IQR, 70–100%), 90% (IQR, 80–100%), and 90% (IQR, 70–100%), respectively. There was no significant difference in the ventilation success rate among the three groups ($\chi^2 = 0.634, P = 0.73$) (Table 2).

| Group    | N  | Successful numbers | M  | Q1 | Q3   | $\chi^2$ | P value |
|----------|----|--------------------|----|----|------|----------|---------|
| 90° PA   | 150| 133                | 100| 70 | 100  | 0.634    | 0.73    |
| 95° PA   | 150| 134                | 90 | 80 | 100  |          |         |
| 100° PA  | 150| 132                | 90 | 70 | 100  |          |         |

M = median; Q1 = the first quartile; Q3 = the third quartile.

Table 2
Comparison of the ventilation success rate between groups (%)

4. Discussion

This airway opening device is innovative equipment with the characteristics of automatic, non-invasive, user-friendly control, multi-functional and extensive application range. What's more, our work hinted that the device can effectively open the airway of the Resusci Anne and the median ventilation success rate of participants was very high regardless of the 90°, 95°, or 100° PA group.

The device has passed the rigorous testing of Chongqing Medical Device Quality Inspection Center (No. WT 202118), which demonstrated its functions and qualities are reliable and practical. The combinations of the above five primary functions of the device and its multiple distinctive characteristics make it different from other airway opening devices\(^{14–17}\). Several airway opening devices have been reported in the previous literature. Deshpande et al. developed a device that can protect the cervical spine, maintain airway patency, and save manpower using a jaw-thrust maneuver\(^{14}\). It is mainly used to open the airway in patients with airway obstruction. Lubovsky et al. developed a device called “Lubo collar”, which can protect the cervical spine while opening and keeping the airways open\(^{15}\). It is mainly suitable for unconscious patients with airway obstruction and/or spinal injury. Cattano et al. developed a rapid airway management positioner to improve the glottic views during laryngoscopy in obese patients by placing the patient in the ramped position\(^{16}\). Von Goedecke et al. developed a Jaw-Thrust-Device to maintain an open airway by keeping the patient's jaws in an optimum position, which is mainly used in patients with mask ventilation\(^{17}\). However, our device has more comprehensive functions and a wider range of applications due to the differences in design background and theoretical basis with the above. Specifically, the design of our device combined two familiar and significant principles of clinical
practices, rather than just one as other devices did. Compared with other devices, our device has a wider range of applications, such as bronchoscopy, tracheal intubation, difficult intubation, etc. Besides, our device opens the airway by automatically adjusting the patient’s position instead of imitating the jaw-thrust maneuver. Previous studies have found that there were some problems when health care workers using manual methods to open the airway, such as incorrect opening techniques, inadequate airway opening, even invalid airway opening\textsuperscript{4,5}, which may delay the treatment process of critically ill patients and threaten their safety. However, our device provides a possible solution for these problems since it opens the airway automatically instead of manually, and it can also free the hands of medical staff and alleviate their fatigue\textsuperscript{14,15}.

In this study, we found that when the degrees of PA were 90.13 ± 0.33, 95.18 ± 0.26, and 100.34 ± 0.31, the median ventilation success rate of participants was 100%, 90%, and 90%, respectively, and there was no significant difference in the three groups. These findings demonstrated that the device has good effectiveness in opening the airway of human manikins. However, further researches need to be conducted to evaluate its efficacy and safety in clinical patients. Since the 1960s, human manikins have been used to teach and train people’s techniques in airway management and CPR, but there are some differences in airway anatomy and mechanics between the real patients and human models\textsuperscript{18,19}. The main differences are the cervical spine mobility, airway resistance, and anatomical proportions, especially the airspace of pharyngeal and retropalatal of human models are wider than the real patients\textsuperscript{20,21}. Therefore, although the device can efficiently open the airway of human manikins, it is not clear whether our results can be extrapolated to clinical patients. Currently, our researches on the device are in the preliminary stage. We think that it is necessary to conduct this manikin study, and our findings are the basis for future clinical trials.

Our work has several limitations. First, the sample size was small. Since it was a pilot study, only 15 volunteers were recruited, which may cause some deviations in the results. Thus, we organized all participants to receive standard operating instructions before the study began to control other influence factors. Second, there were no randomized control groups. In this study, we didn’t randomly assign participants to three different levels of the PA, so we can’t rule out the influence of the study sequence on the results. Besides, we couldn’t compare the superiority and inferiority of airway opening between the device and the manual methods. Similarly, we couldn’t compare the performance of our device with other devices, considering the uniqueness of the research fields and the low feasibility of comparative experiments. Third, the quantified outcome measures were inadequate. Before formulating the research plan, we used the received tidal volume of human manikins as the outcome measurement to increase the reliability of the results, but we had to exclude it since the Resusci Anne isn’t equipped with an instrument to measure it.

5. Conclusion

In conclusion, a novel airway opening device has been designed, developed, tested, and functionally evaluated using a human manikin. Health care providers can use the device automatically and effectively
open and maintain the patent airway of human manikins, thus freeing their hands, alleviating fatigue, and appropriately compensating for the incorrect, inadequate, or ineffective operation in the manual airway opening methods. Finally, this study can provide important references for us to further detect its efficacy and safety in clinical patients.

Declarations

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Author contributions

Chen designed the study, collected data, analyzed data, and written original draft. Luo collected data and edited writing draft. Li collected data and edited writing draft. Sun collected data. Yang designed the study, edited writing draft, and took responsibility for the integrity of the work as a whole.

Conflict of interest statement

The first and corresponding authors are one of the inventors of the “Airway Opening Device with Automatic Position Adjustment” (Patent authorized publication number: CN110279551B). None of the other authors have rights or any kind of benefits from this patent.

Data availability

Anonymized data are available for external analysis from the corresponding author upon request.

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