INTRODUCTION

Endotracheal intubation is an essential life-saving intervention, and unplanned endotracheal extubation (UEE) is one of the most frequent incidents reported among the patients with endotracheal intubation. According to incomplete statistical analyses, UEE has high incidence, ranging from 3.4% to 22.5% (Kwon & Choi, 2017; Yeh et al., 2004). UEE may result in serious harm, including dyspnea, airway trauma, laryngeal and tracheal edema, difficult reintubation, hospital-acquired infections and even death (Aydogan & Kaya, 2017; Kiekkas et al., 2013).

Reducing the rate of UEE is an important goal in nursing management in the ICU (Chang, Liu, Huang, Yang, & Chang, 2011). The purpose of the study was to help nurses identify patients with high UEE risk; then, they can take active intervention measures at the first time to prevent UEE so as to promote patient safety.

BACKGROUND

Although the reasons for UEE has been discussed in numerous studies, to the best of our knowledge, there is no single valid and reliable tool for assessing the risk of UEE in patients with endotracheal intubation. In 2004, Moons developed the self-extubation risk assessment tool (SERAT) but found it to be insufficient in clinical practice (Moons et al., 2008). Although the tool can correctly identify patients who perform intentional self-extubation, the number of false positives in their evaluation is large, so SERAT is not recommended...
to use in clinic to prevent invasive interventions in patients who are not at risk of unplanned extubation.

The rate of UEE is the key element of quality control indicators in critical care medicine specialty (Rhodes et al., 2012; Yang et al., 2019). Therefore, it is necessary to establish an effective assessment tool to identify risk factors considered to be highly associated with UEE.

3 | METHODS

3.1 | Design

The Delphi method is a structured process used to record the opinions of a group of experts through iterative inquiries, then summarized and shared the results in a subsequent inquiry until a consensus was reached. It is widely recommended for use in medicine. And for this study, a questionnaire was prepared by the investigator. The experts exchanged their opinions anonymously through letters and then provided suggestions. The consultant group collected the judgments and opinions of the experts, analyzed them and feedback. Repeated inquiries and collected opinions of feedback, until the expert group finally reached a reliable consensus.

We implemented a Delphi method to record experts' opinions about what should be considered as the critical risk factors on UEE in artificial airway patients.

3.2 | Screening of initial indicators

We searched various databases, including cnki.net, Wan Fang, PubMed, web of science, with related keywords (endotracheal intubation, artificial airway, accident extubation, unplanned extubation, unintended extubation, etc.) for original papers and published from 2000 to 2019. Meanwhile, we analyzed the cases of UEE, which occurred in our hospital in past 5 years. We set the initial scale after many discussions among the consultant group. Furthermore, five ICUs in our hospital were selected to test the initial scale, in which 10 clinical nurses and 5 head nurses worked in ICU more than 5 years were selected to complete the scale pre-survey. Based on the comprehensive analysis of the pre-survey results, the research team further revised and improved the scale, forming an updated scale with 13 primary indicators and 38 secondary indicators.

3.3 | Consultant group

We gathered a research group consisted of five members. The person in charge is a RN, MSN, an associate professor with 15 years of teaching and research experience and 29 years of clinical experience. There are 3 RN who have worked in ICU more than 10 years, including 2 postgraduate students, another is the head nurse with a graduate degree. There is also a doctor, PhD, an associate professor worked in ICU more than 15 years. The group discussed the initial scale, formed the expert inquiry questionnaire and developed the final scale based on expert consultations through two rounds of Delphi.

3.4 | Delphi panel

The original expert panel consisted of 18 nurse experts from 13 tertiary-A hospitals in eight provinces (Sichuan, Chongqing, Hubei, Guangdong, Shanghai, Hebei, Shanxi, Xinjiang). They worked in ICU more than 10 years, had a bachelor's degree or above, held a post of associate senior or associate professor or above and were willing to participate in this study.

3.5 | Data collection

Two rounds of questionnaires were delivered via email in July and August 2019. Experts were asked to complete the questionnaire in two weeks each round, and reminders were emailed at the beginning. There was a two-week interval between two rounds, to ensure that the consultant group have sufficient time to analyze, summarize and feedback expert opinions. The questionnaire encompassed three sections: (1) an explanation of the research goal and instructions; (2) content of the scale, including the importance of first-level indicator and the reasonableness of the second-level indicator were assessed by a five-point Likert scale, where 5 points means that it is very important or reasonable, and 1 point indicates it is not at all. A blank was left after each indicator for panelists write down their views about revisions, additions, or deletions; and (3) the demographic information about the panelists was recorded.

Indicators were considered by consultants, which a mean coefficient of >3.5 indicate the importance and variation of <0.25 indicate a low level of variability in the panel members' opinions and will be incorporated into the second round, if not, experts'
opinions shall be referred, and supplementary literature retrieval shall be conducted to demonstrate the scientificity of relevant suggestions. Achievement of a consensus is the standard for completing the Delphi process. On one hand, consensus was defined as the score of the first-level indicators’ importance and the score of the second-level indicators’ appropriate degree of assignment ≥4 was awarded by >67% of the panelists (Hughes et al., 2020; Koch et al., 2020). On the other hand, the coefficient of variation (CV) and the Kendall coefficient of concordance (W) reflect the degree of agreement.

3.6 | Statistical analysis

The mean ± standard deviation (SD) and coefficient of variation (CV) were determined for each indicator in two rounds. The Kendall coefficient of concordance (W) was used to evaluate the level of agreement among the experts. All statistical analyses were carried out with Excel 2016 and IBM SPSS statistical software version 25.0. A two-tailed p-value < .05 was considered statistically significant.

3.7 | Ethical considerations

This study was supported by the Ethics Committee of the First Affiliated Hospital of Chongqing Medical University.

4 | RESULTS

4.1 | The characteristics of panelists

All 15 panelists responded two rounds inquiry. Most of them are female (n = 13, 86.7%) and head nurses (n = 14, 93.3%). Their mean age was 46.5 ± 4.5 years, the work experience was 27.5 ± 5.2 years, and there were 4(26.7%) people with master’s degree. Their areas of work are nursing management, clinical nursing and nursing education (Table 1).

| Age(years)       | N (%) |
|-----------------|-------|
| 40              | 3(20) |
| 41-50           | 10(67)|
| >50             | 2(13) |

| Sex             | N (%) |
|-----------------|-------|
| Female          | 13(86.7)|
| Male            | 2(13.3)|

| Work experience in ICU (years) | N (%) |
|-------------------------------|-------|
| 16–20                         | 3(20) |
| 21–30                         | 7(46.7)|
| >31                           | 5(33.3)|

| Educational attainment | N (%) |
|------------------------|-------|
| Master                 | 4(26.7)|
| Bachelor               | 11(73.3)|

| Title        | N (%) |
|--------------|-------|
| Deputy senior| 14(93.3)|
| Senior       | 1(6.7) |

4.2 | The enthusiasm of experts

The enthusiasm of experts was said by the response rate. In the first round, 16 of 18 panelists returned, and the response rate was 88% (16/18). Two panelists were excluded because of their invalid answers. In the second round, the response rate was 94% (15/16), one panelist dropped out for individual reason.

4.3 | The authority of experts

The authority coefficient (Cr) of the expert is the arithmetic mean of the expert judgment coefficient (Ca) and expert familiarity degree (Cs). The Cr of the first round is 0.94 and the Cr of the second round is 0.96, indicating that the results could be considered reliable.

4.4 | Degree of coordination of experts

The degree of coordination of experts was determined using W and CV values for each round and the consistency was determined by score ≥4 was awarded by >67% of the panelists. The w-value for concordance in the two rounds ranged from 0.224 to 0.352(all p < .001), indicating consensus among the panelists (Table 2). The score and CV of each first-level indicator and each second-level indicator were showed in Table 3 and Table 4 respectively.

4.5 | Revision of indicators

Based on panelists’ suggestion, we amended the second-level indicators which in first-level indicator “consciousness” to the following four states: “deep coma/in a coma”, “awake”, “lethargy and shallow coma” and “confusion/delirium”. The first-level indicator “emotion” was changed to “emotional and mental state”, and a second-level indicator “depression or mania” was added. The first-level indicator “pain” was changed to “pain and discomfort”, and the second-level indicators have also been adjusted accordingly.

The first-level indicators "sex" and "age" were removed, because the CV of them were >0.25 in both two rounds panel. After two rounds of expert panel, their opinions tended to be consistent. 11 first-level indicators and 34 second-level indicators were identified (Table 3, Table 4).
TABLE 3 The importance of each first-level indicator

| Indicators                        | Mean | Score ≥4, N (%) | SD  | CV  |
|-----------------------------------|------|-----------------|-----|-----|
| Consciousness                     | 4.93 | 15(100)         | 0.25| 0.05|
| Upper limb strength               | 4.73 | 15(100)         | 0.44| 0.09|
| Sex*                              | 2.20 | 17(7)           | 0.98| 0.28|
| Age*                              | 3.33 | 6(40)           | 0.94| 0.08|
| Physical restraint                | 4.80 | 15(100)         | 0.40| 0.08|
| Pain or Discomfort                | 4.87 | 15(100)         | 0.34| 0.07|
| Emotional or mental state         | 4.93 | 15(100)         | 0.25| 0.05|
| Route of tracheal intubation      | 4.33 | 15(100)         | 0.47| 0.11|
| Method used for performing intubation | 4.80 | 15(100)     | 0.40| 0.08|
| Ventilator or not                 | 4.20 | 12(80)          | 0.91| 0.22|
| Viscosity of sputum               | 3.73 | 9(60)           | 0.85| 0.23|
| Presence of a respiratory disease | 3.87 | 10(67)          | 0.88| 0.23|
| The number of days with intubation | 3.93 | 10(67)         | 0.77| 0.20|

The indicators which marked *** were removed at last

5.2 Scientific-ness of the indicators

The initial scale consisted of 13 first-level indicators based on the literature review and clinical experience, "sex" and "age" were proposed in many studies about UEE but were ultimately eliminated. The majority of patients who experienced extubation were male (Ai et al., 2018; de Groot et al., 2011; Jarachovic et al., 2011). Some studies showed that UEE is more common in younger people (Chuang et al., 2015; Kwon & Choi, 2017), while other study showed that "age" and "sex" are not associated with UEE (Aydogan & Kaya, 2017). In this study, there was still a dispute about whether the two factors were related to UEE. The mean scores of the two indicators were less than 3.5 and the CV were greater than 0.25, so these indicators were finally eliminated.

Patients with GCS (Glasgow Coma Scale, GCS) ≥9 under high risk, especially patients with disorientation and cognitive impairment such as confusion or delirium (Ai et al., 2018; Moons et al., 2004), so it is necessary to assess the consciousness degree and the existence of delirium.

The MRC (Medical Research Council) scale of muscle strength pointed that grade 3 and above can active movement against gravity (Compston, 2010), so they have the ability to extubate themselves.

Physical restraints remain the first choice when there is a high risk of UEE. But they were still happened even when physical restraints were used, whether physical restraints can prevent UEE is debated worldwide. The primary risk factor of UEE is the patient’s ability to move freely (Song & Yun, 2015). In this study, we based on the constraint decision wheel used in Canada, the types of constraints were categorized into four levels in order from weak to strong: unconstrained/fourth-order; third-order constraint; second order constraint; first-order constraint according to the function of the constraints and the movement after restraints (Hurlock-Chorostecki & Kielb, 2006).

Pains and discomfort increase the risk of UEE and increase the opportunity of delirium or restlessness. Patients in ICU suffer from a variety of uncomfortable and painful conditions such as that come with endotracheal intubation and kinds of treatment may led to agitation and delirium. Agitation and delirium increase the risk of UEE directly (Kwon & Choi, 2017), meanwhile the increased needs due to discomfort, and desire to communicate also increase the risk of UEE (Danielis et al., 2018). The six kind of commonly used pain scales (Behavior Pain Scale [BPS]; Pain Assessment Behavioral Scale with Numeric Rating Scale [NRP]; etc.) are valid and sensitive for assessing pain severity in both communicative and non-communicative patients (Rahu et al., 2015). Assessment is the basis

5 | DISCUSSION

5.1 The reliability of the expert panel

This study strictly followed the principle of the Delphi method from the selection of experts, the distribution of questionnaire, to the collection opinions of feedback opinion, the revision of scale and repeated inquiries, to ensure the reliability of the conclusion. Experts in this study come from eight provinces in the East, West, North and South of China, so their opinions were regionally representative. The positive coefficient of experts in both rounds were 88% and 94%, and most experts put forward their opinions, indicating the great attention and support for this study. The authority coefficients of the two rounds were >0.8, the higher coefficient, the better authority and representation. The coordination of expert opinions in first-level indicators were 0.224 and 0.241 in two rounds, respectively. Meanwhile, the coordination in second-level indicators were 0.323 and 0.352 in two rounds, respectively (all p < .001). The results of statistical analysis showed that the opinions of experts have reached a consensus (Gao et al., 2018).
for any intervention. So, it is essential to assess the degree of pain or discomfort, then taking appropriate analgesic and sedative measures after eliminating discomfort factors.

Patients in ICU often have anxiety related to multiple sources, including disease, alarms, noise, etc. Anxiety increased agitation and incidence of UEE (King & Elliott, 2012). Besides, lacking of the

### TABLE 4 Appropriate degree of assignment of second-level indicators

| Second-level indicators                                      | Assignment score | Mean Score | Score ≥4, N (%) | SD  | CV  |
|--------------------------------------------------------------|------------------|------------|-----------------|-----|-----|
| deep coma/in a coma                                          | 0                | 4.20       | 11(73)          | 1.01| 0.24|
| awake                                                        | 1                | 4.53       | 15(100)         | 0.52| 0.11|
| lethargy and shallow coma                                    | 2                | 4.47       | 13(87)          | 0.74| 0.17|
| confusion/delirium                                           | 3                | 4.93       | 15(100)         | 0.26| 0.05|
| Upper limb strength level 0-2                                | 0                | 4.40       | 12(80)          | 1.06| 0.24|
| Upper limb strength level 3                                   | 1                | 4.20       | 11(73)          | 1.01| 0.24|
| Upper limb strength level 4-5                                 | 2                | 4.67       | 15(100)         | 0.49| 0.10|
| Female*                                                       | 1                | 3.13       | 5(33)           | 1.41| 0.45|
| Male*                                                        | 2                | 3.20       | 5(33)           | 1.32| 0.41|
| Non-high-risk age*                                            | 1                | 3.20       | 6(40)           | 1.26| 0.40|
| High-risk age (≥60y)*                                         | 2                | 3.47       | 8(53)           | 1.41| 0.41|
| unconstrained/fourth-order                                    | 0                | 4.53       | 13(87)          | 1.06| 0.23|
| third-order constraint                                        | 1                | 4.26       | 12(80)          | 0.96| 0.23|
| second order constraint                                       | 2                | 4.20       | 10(67)          | 0.94| 0.22|
| first order constraint                                        | 3                | 4.33       | 11(73)          | 1.05| 0.24|
| No pain (discomfort)                                         | 0                | 4.40       | 11(73)          | 0.91| 0.21|
| Mild pain (discomfort)                                       | 1                | 4.33       | 11(73)          | 0.90| 0.11|
| Moderate pain (discomfort)                                   | 2                | 4.60       | 14(93)          | 0.63| 0.14|
| Severe pain (discomfort)                                     | 3                | 4.87       | 14(93)          | 0.52| 0.11|
| Emotional stability (positive and optimistic, compatible with treatment, good compliance with treatment) | 0                | 4.33       | 12(80)          | 0.98| 0.23|
| Irritability, tension or anxiety                              | 1                | 4.73       | 14(93)          | 0.59| 0.13|
| Fear, irritability, low adherence to treatment, depression or mania | 2                | 4.93       | 15(100)         | 0.26| 0.05|
| Tracheotomy                                                  | 1                | 4.07       | 12(80)          | 1.03| 0.25|
| Nasal intubation                                              | 2                | 4.47       | 14(93)          | 0.64| 0.14|
| Oral intubation                                               | 3                | 4.73       | 15(100)         | 0.46| 0.10|
| Endotracheal Tube Holder                                      | 1                | 4.20       | 11(73)          | 0.86| 0.21|
| tie and tape/tie                                             | 2                | 4.33       | 14(93)          | 0.62| 0.14|
| Adhesive Tape                                                | 3                | 4.47       | 14(93)          | 0.64| 0.14|
| No ventilator                                                | 0                | 3.67       | 7(47)           | 1.11| 0.30|
| ventilator                                                   | 1                | 4.07       | 9(60)           | 1.10| 0.27|
| Semifluid secretions                                         | 0                | 3.33       | 8(53)           | 1.45| 0.43|
| Sticky secretions                                            | 1                | 3.47       | 9(60)           | 1.41| 0.41|
| Thick secretions                                             | 2                | 3.73       | 11(73)          | 1.39| 0.37|
| No respiratory disease                                       | 0                | 3.53       | 8(53)           | 1.25| 0.35|
| Have respiratory disease                                     | 1                | 3.73       | 9(60)           | 1.03| 0.28|
| Intubated for ≤ 3 days                                       | 1                | 4.13       | 11(73)          | 0.99| 0.24|
| Intubated for 4-7 days                                       | 2                | 4.27       | 11(73)          | 1.03| 0.24|
| Intubated for ≥8 days                                        | 3                | 4.33       | 12(80)          | 0.98| 0.23|

The indicators which marked *** were removed at last.
knowledge of endotracheal tube and the use of physical restraints make the patients fear, agitated and irritability. In addition, the long stays in ICU make them depression, even losing confidence in treating the disease. As we all know emotions and mental states command people's behavior. Patients with mental illness are clinically recognized as having a high risk of UEE (Moons et al., 2004), they have cognitive dysfunction in different degree may perform unbelievable behavior. Assess patients' emotion and mental state is the basis for ensuring patient safety.

The route of tracheal intubation affects patient's tolerance and compliance. Tracheotomy can improve the comfort of patients, and the patients intubated via the mouth were more agitated and more often the UEE happened than the patients through nasotra- cheal route (Ben et al., 2011; Chevron et al., 1998). The appropriate tube placement way should be selected according to the patient's condition.

The intubation days also influence the risk of UEE. Epstein stated that the longer intubation days, the higher risk of self-extubation, and the higher need for close observation (Epstein et al., 2000). Aydoğan also found the longer intubation days, the higher risk of UEE (Aydogan & Kaya, 2017). So, it is essential to assess the need for intubation, and encourage patients to overcome the discomfort, pessimism and disappointment. At the same time, be vigilant and follow-up closely.

Ventilator or not plays an important role in UEE. Daily sedation interruption in mechanically ventilated critically ill patients was widely performed, and proved to be safe and beneficial to the facilitation of the weaning process (Vagionas et al., 2019). During the weaning trails, with the decrease of sedative drugs and the increase of consciousness level, the risk of self-extubation increased. On another hand, patients with ventilator increase the difficulty of catheter care. When changing positions and transporting, the lack of effective protection or buffer length can easily cause the catheter to fall out.

Patients with respiratory disease has higher risk of respiratory infection and respiratory failure. Compared with people without respiratory disease, the tracheal intubation time is prolonged obviously (Chuang et al., 2015). At the same time, large amounts of sputum secretion require regular sputum aspiration, which reduces the patient's tolerance. Once lacking of effective heating and humidifying, thick sputum increases the opportunity of blocking the tube. Patients cannot be ventilated with a manual resuscitator and in whom suction cannot be performed due to a blockaged tracheal tube; they cannot be resuscitated, and airway obstruction can occur, leading lethal complications (Mirkheshti et al., 2014). Blocked tubes contribute to one-third of all airway accidents, and they are often blocked by thick secretions; most patients with blocked tubes require reintubation (Kapadia et al., 2014). Therefore, it is important to assess the stickiness of secretion.

Some panelists mentioned that the "RASS score" should be added as a first-level indicator. After the group discussion, it was decided that the content of the "RASS score" and the content of the first-level indicator "consciousness" and "emotional or mental state" overlapped. Therefore, it was not included.

5.3 The practicability of the evaluation index system

Nursing assessment is the first step in clinical nursing. Only when high-risk patients are identified, can we take targeted measures to implement interventions to avoid physical and economic harm to patients and reduce the rate of UEE. All indicators such as consciousness, upper limb strength, physical restraint, pain/discomfort, and so on, are the focus of ICU patients' shifts, which are easy for nurses to understand and implement.

6 LIMITATIONS

Anyway, this study had several limitations. First, there were still some second-level indicators which showed mean coefficient of <3.5 and the variation of >0.25, but we still reserved them. Because the literature retrieval and clinical experience confirmed that they were indeed meaningful in UEE, whether they have any significance in finding high-risk patients with UEE will be evaluated by later clinical application. Second, the values reported in Table 2 indicate relatively low W-values, but it also acceptable (Gao et al., 2018). Third, this tool has not been applied in patients with endotracheal intuba- tion. Future research will evaluate its effect and improve this assessment tool in clinical practice.

7 CONCLUSION

An unplanned extubation assessment tool for endotracheal intuba- tion patients constructed in the study is scientific, practical and operable. It is significance for clinical nurses to assess the risk of UEE, and to improve their risk awareness for assuring patient safety and improving the ICU nursing quality. The indicators in this study need to be further tested in practice, verified and revised in clinical applications. Subsequent research should select several hospitals to apply this tool to verify its feasibility and scientific- ness.

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CONFLICTS OF INTEREST
The authors declare that they have no conflicts of interest.

DATA AVAILABILITY STATEMENT
Data are available on reasonable request from the authors. Full data set available from the corresponding author at 840804395@qq.com.

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