Clinical research protocol

Project name: Application of PDCA Cycle in Tracheal Intubation Training for Emergency Medicine Residents

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Department: emergency

Research period: October 1 2024 to September 30 2025NCT No.: none.

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Abstract

object name	Application of PDCA Cycle in Tracheal Intubation Training for Emergency Medicine Residents
goal of study	Tracheal intubation is a high-risk, time-sensitive procedure essential in emergency airway management. Junior emergency medicine (EM) residents often face challenges in mastering this critical skill. The Plan–Do–Check–Act (PDCA) cycle is a structured educational framework that may enhance procedural competency through iterative improvement. This study aimed to evaluate the impact of a PDCA-based training model on intubation performance among EM residents.
research design	This was a prospective observational study conducted in the emergency department (ED) of a tertiary teaching hospital. A PDCA-based clinical skills training program was formally implemented in the department beginning in October 2024. Residents who performed tracheal intubation procedures from October 2023 to September 2023 were assigned to the control group, representing training prior to PDCA implementation. Those who performed intubations from October 2024 to September 2025 constituted the intervention group, following the adoption of the PDCA cycle teaching model. Outcomes were compared between groups, including: success and failure rates of tracheal intubation,procedure completion time,incidence of airway-related local trauma or bleeding,reintubation within 3 days due to airway injury, and resident satisfaction with training. The study protocol was approved by the institutional ethics committee. Written informed consent was obtained from all participants, and all procedures complied with the Declaration of Helsinki

	(2013).umulative hospitalization time and mortality were collected.
Total number of cases studied	100 cases
case selection	Inclusion Criteria: Emergency medicine residents rotating in the emergency department during the study period. Residents who are required to perform tracheal intubation as part of clinical training. Residents who have completed baseline theoretical and simulation-based airway management training. Voluntary participation with written informed consent. Exclusion Criteria: Residents who refuse to participate or withdraw consent. Residents with prior advanced airway fellowship training or extensive intubation experience (>50 independent intubations). Residents who are unable to complete the full PDCA-based training program due to absence or rotation schedule. Any medical condition or circumstance deemed by investigators to interfere with participation or data integrity.
	excluded criteria: 1 combined with neurogenic shock, trauma and hemorrhagic shock; 2 symptomatic patent ductus arteriosus; 3 combined with congenital heart disease; 4 give up treatment or death within 24 hours of admission; 5 The legal guardian refused to participate in the study; 6 Key information and information missing.
Treatment plan	This was a prospective observational study conducted in the emergency department (ED) of a tertiary teaching hospital. A PDCA-based clinical

	skills training program was formally implemented in the department beginning in October 2024. Residents who performed tracheal intubation procedures from October 2023 to September 2023 were assigned to the control group, representing training prior to PDCA implementation. Those who performed intubations from October 2024 to September 2025 constituted the intervention group, following the adoption of the PDCA cycle teaching model.
efficacy evaluation	The main efficacy indicators: success and failure rates of tracheal intubation, Secondary efficacy indicators: procedure completion time,incidence of airway-related local trauma or bleeding,reintubation within 3 days due to airway injury, and resident satisfaction with training.
statistical method	All statistical analyses were performed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Categorical variables, including intubation success rate, incidence of local airway trauma, extubation failure due to airway injury, and resident satisfaction rate, were expressed as counts and percentages [n (%)], and were compared between groups using the chi-square test (χ^2 test) or Fisher's exact test, as appropriate. Continuous variables, such as intubation completion time, were tested for normality using the Shapiro–Wilk test. Variables not conforming to a normal distribution were expressed as median (interquartile range) and compared using the Mann–Whitney U test. A two-tailed P value < 0.05 was considered statistically significan Exclusion Criteria • Residents who refuse to participate or withdraw

	informed consent. • Residents with prior advanced airway fellowship training or extensive intubation experience (>50 independent intubations). • Residents unable to complete the full PDCA-based training program due to absence, scheduling conflicts, or early rotation termination. • Residents with medical conditions or personal circumstances that could interfere with participation or data collection integrity.
Research period	October 2024 1 to September 30 2025

一、Research background

Tracheal intubation is a cornerstone of emergency airway management, critical in conditions such as cardiac arrest, trauma, respiratory failure, and airway obstruction(1–3). Despite its lifesaving role, tracheal intubation remains one of the most technically challenging procedures for emergency medicine (EM) residents(4–6). Studies have consistently shown that junior residents face difficulty in achieving first-pass success, often resulting in repeated attempts, airway trauma, hypoxia, aspiration, and adverse patient outcomes(2,7–10). The steep learning curve, high cognitive load, and pressure inherent to emergency settings further exacerbate the risk of procedural failure(11–13).

Traditional didactic training often lacks the iterative reinforcement and feedback required for skill retention and real-time adaptation(14–15). In response, the Plan–Do–Check–Act (PDCA) cycle, originally introduced by Deming for industrial quality improvement, has been adopted in medical education to improve procedural competency(16–18). The PDCA framework promotes continuous evaluation and refinement of teaching strategies, aligning well with modern competency-based medical education paradigms(19–21).

Recent applications of PDCA in healthcare simulation and airway management training have demonstrated significant benefits, including improved first-pass success rates, reduced complication incidence, and enhanced learner satisfaction(22–29). Particularly in pediatric and neonatal intensive care units, PDCA-guided programs have standardized procedural education and bridged the gap between theory and practice(25–26). However, its integration into emergency airway training—a domain defined by unpredictability, urgency, and complexity—remains

underexplored(30–34).

二、research objective

This study aims to evaluate the impact of a PDCA cycle-based tracheal intubation training model for EM residents. We hypothesize that such structured, iterative, and feedback-driven training can significantly enhance intubation success, procedural efficiency, safety, and trainee confidence in high-stakes emergency environments.

三、Research Design Types, Principles, and Test Procedures

1. Research Design

This was a prospective observational study conducted in the emergency department (ED) of a tertiary teaching hospital. A PDCA-based clinical skills training program was formally implemented in the department beginning in October 2024. Residents who performed tracheal intubation procedures from October 2023 to September 2023 were assigned to the control group, representing training prior to PDCA implementation. Those who performed intubations from October 2024 to September 2025 constituted the intervention group, following the adoption of the PDCA cycle teaching model.

四、case selection

Inclusion Criteria:

(1) Emergency medicine residents rotating in the emergency department during the study period.

(2) Residents who are required to perform tracheal intubation as part of clinical training.

(3) Residents who have completed baseline theoretical and simulation-based airway management training.

① Voluntary participation with written informed consent.

Exclusion Criteria:

(1) Residents who refuse to participate or withdraw consent.

(2) Residents with prior advanced airway fellowship training or extensive intubation experience (>50 independent intubations).

(3) Residents who are unable to complete the full PDCA-based training program due to absence or rotation schedule.

(4) Any medical condition or circumstance deemed by investigators to interfere with participation or data integrity.

Exclusion Criteria

- Residents who refuse to participate or withdraw informed consent.
- Residents with prior advanced airway fellowship training or extensive intubation experience (>50 independent intubations).
- Residents unable to complete the full PDCA-based training program due to absence, scheduling conflicts, or early rotation termination.
- Residents with medical conditions or personal circumstances that could interfere with participation or data collection integrity.

五、research method

This was a prospective observational study conducted in the emergency department (ED) of a tertiary teaching hospital. A PDCA-based clinical skills training program was formally implemented in the department beginning in January 2024. Residents who performed tracheal intubation procedures from January 2023 to December 2023 were assigned to the control group, representing training prior to PDCA implementation. Those who performed intubations from January 2024 to December 2024 constituted the intervention group, following the adoption of the PDCA cycle teaching model.

Outcomes were compared between groups, including: success and failure rates of tracheal intubation,procedure completion time,incidence of

airway-related local trauma or bleeding,reintubation within 3 days due to airway injury, and resident satisfaction with training.

The study protocol was approved by the institutional ethics committee. Written informed consent was obtained from all participants, and all procedures complied with the Declaration of Helsinki (2013).

PDCA Cycle-Based Training Intervention

1.1 Clinical Case Example for Tracheal Intubation

A 64-year-old male presented to the ED via emergency medical services with a 20-minute history of sudden loss of consciousness and respiratory distress. His past medical history included poorly controlled hypertension and coronary artery disease. On arrival, he was comatose (GCS score: 6, E1V1M4), with SpO_2 82%, respiratory rate 10 breaths/min, blood pressure 100/50 mmHg, and heart rate 112 bpm. Pupils were equal and reactive to light, but sluggish. Lung auscultation revealed diminished breath sounds with coarse rales bilaterally; cardiac rhythm was regular.

Arterial blood gas revealed: pH 7.18, $PaCO_2$ 62 mmHg, PaO_2 49 mmHg, HCO_3^- 21 mmol/L. Cranial CT excluded intracranial hemorrhage. A preliminary diagnosis included altered mental status, acute respiratory failure (likely mixed central and pulmonary etiology), and possible acute heart failure. To prevent airway obstruction, aspiration, and further hypoxic brain injury, the emergency team initiated invasive hemodynamic monitoring and decided to proceed with immediate tracheal intubation.

1.2 Teaching Implementation

Given the patient's critical condition, prompt establishment of a secure airway via endotracheal intubation was required. Informed consent was obtained from the patient's family after brief explanation by the attending physician. The procedure was performed at the bedside by an emergency

medicine resident who had completed standardized intubation training and was supervised by a senior attending. The training and management approach followed the four stages of the PDCA cycle:

Stage 1: Plan

To enhance residents' competency in tracheal intubation, the emergency department developed a structured PDCA-based training protocol:

(1) Didactic Sessions: Weekly theoretical instruction was conducted by senior attending physicians in small-group settings every Wednesday afternoon. Topics included indications and contraindications of adult intubation, airway anatomy, identification of difficult airway, rapid sequence induction (RSI), and management of complications.

(2) Simulation Training: Every Thursday, high-fidelity airway mannequins were used for hands-on simulation of various clinical scenarios (e.g., COPD exacerbation, upper gastrointestinal bleeding, comatose patients). Instructors demonstrated procedures, emphasized key actions and safety checkpoints, and provided immediate corrective feedback during resident practice.

(3) Clinical Practice: Residents were allowed to perform intubations in clinical settings only after passing theoretical and simulation assessments. Based on experience level, instructors assigned appropriate cases. Stable patients with lower intubation difficulty were prioritized for beginners, with gradual progression to more complex scenarios.

Stage 2: Do

In the case described above, the patient met criteria for emergent intubation due to coma and hypoxemia. A pre-intubation airway assessment showed Mallampati class II, acceptable neck mobility, and no oropharyngeal

deformities. Equipment prepared included: bag-valve mask, laryngoscope, 7.5 mm endotracheal tube, stylet, lubricating gel, induction drugs, crash cart, and vital sign monitors.

Under direct supervision, the trained resident performed RSI and successfully completed intubation within 15 seconds. Tube placement and depth were confirmed and mechanical ventilation was initiated. Post-procedure chest X-ray verified correct tube position, and ventilatory management was continued.

We analyzed 98 intubation procedures performed by residents in 2023 (control group) and 103 procedures in 2024 after PDCA implementation (intervention group), comparing outcomes as outlined above.

Stage 3: Check

The effectiveness of PDCA implementation was assessed through both process monitoring and outcome evaluation. Data collected from the intervention group were compared to baseline data from the control group.

Definitions:

Successful intubation: Independent completion of tracheal intubation by the resident following standard operating procedures.

Failed intubation: Three or more unsuccessful attempts to pass the endotracheal tube to appropriate depth.

Airway trauma: Presence of fresh blood in the airway post-intubation, excluding bleeding from preexisting pathology (e.g., subglottic mass, pulmonary hemorrhage).

Extubation failure due to airway injury: Need for reintubation within 72 hours despite meeting extubation criteria, confirmed by laryngoscopic evidence of edema, vocal cord paralysis, granulation, or subglottic stenosis.

Resident satisfaction: Evaluated via anonymous questionnaire covering

subjective learning experience and perceived value of training during their ED rotation.

Stage 4: Act

Based on outcome data and feedback, the following improvements were implemented in the subsequent PDCA cycle:

(1)Simulation Enhancement: Increased frequency of practice sessions for novice residents; established a “failed simulation bank” focused on difficult airway scenarios.

(2)Visualization Tools: Introduced video laryngoscopy into teaching to enhance visualization and facilitate real-time instruction.

(3)Assessment System: Developed a standardized scoring system for intubation performance using instructor ratings, video review, and checklist-based evaluation for closed-loop feedback.

In addition, procedural nursing aspects before and after intubation were emphasized, including:pre-procedure safety checklists,continuous monitoring of vital signs,reinforcement of sterile techniques,timely replacement of tube fixation materials,stabilization of head and body position to prevent tube displacement,and visible labeling of critical lines and tubes.

All such measures were progressively incorporated into the next iteration of PDCA-based training to ensure quality, consistency, and sustainability.

六、Observation items and detection time points

1. First-Attempt Success Rate of Tracheal Intubation

Observation item: Whether residents complete intubation successfully on the first attempt.

Detection time point: Immediately during the procedure, confirmed by chest

rise, end-tidal CO_2, auscultation, or chest X-ray.

2. Intubation Completion Time

Observation item: Time required for residents to complete intubation.

Detection time point: Measured in seconds from insertion of the laryngoscope to confirmation of successful tube placement.

3. Incidence of Local Airway Trauma

Observation item: Presence of visible bleeding or mucosal injury during suctioning after intubation.

Detection time point: Within 24 hours post-intubation.

4. Extubation Failure Due to Airway Injury

Observation item: Need for reintubation caused by airway injury (edema, vocal cord paralysis, granulation, or subglottic stenosis).

Detection time point: Within 72 hours post-extubation.

5. Resident Satisfaction With Training

Observation item: Residents' subjective evaluation of the PDCA training program.

Detection time point: At the end of the emergency department rotation, via anonymous questionnaire.

七、standards for efficacy appraisal

1. Primary Efficacy Standard

First-attempt success rate of tracheal intubation is the primary indicator of efficacy.

An intervention is considered effective if the PDCA-trained group demonstrates a statistically significant improvement compared with the control group ($P < 0.05$).

2. Secondary Efficacy Standards

Intubation completion time: A reduction in median time compared with controls indicates improved procedural efficiency.

Incidence of airway trauma and extubation failure: Lower rates suggest enhanced safety and procedural proficiency, even if not statistically significant.

Resident satisfaction score: Higher satisfaction rates reflect better training experience and improved confidence.

3. Comprehensive Appraisal

The PDCA training program will be deemed efficacious if it results in significant improvement in the primary outcome and favorable trends across multiple secondary outcomes.

Statistical analyses will use chi-square tests for categorical variables and Mann–Whitney U test for continuous variables, with $P < 0.05$ considered statistically significant.

八、Observation of adverse events

1. Adverse Events of Interest

Local airway trauma: visible bleeding, mucosal laceration, or swelling during/after intubation.

Extubation failure due to airway injury: reintubation required within 72 hours caused by laryngeal edema, vocal cord paralysis, granulation tissue, or subglottic stenosis.

Procedure-related complications: hypoxemia (SpO_2 < 90%), aspiration, esophageal intubation, dental injury, or hemodynamic instability (e.g., hypotension, arrhythmia).

Resident-related adverse events: psychological distress, fatigue, or stress-related reactions during high-risk airway procedures.

2. Observation Method

Continuous monitoring of vital signs (SpO_2, heart rate, blood pressure) during and immediately after intubation.

Post-procedure evaluation of the airway via clinical examination, suctioning

records, and laryngoscopic confirmation when indicated.

Extubation follow-up within 72 hours to identify delayed complications.

Resident self-report questionnaires and supervisor observation to capture psychological or human-factor–related adverse events.

3. Recording and Reporting

All adverse events will be recorded in case report forms (CRFs), specifying type, severity, onset time, and outcome.

Serious adverse events (SAEs) will be reported to the institutional ethics committee within 24 hours.

Data will be analyzed to compare incidence rates between the control and PDCA groups.

九、Data security monitoring

Clinical research will develop a corresponding data security monitoring plan based on the size of the risk. All adverse events were recorded in detail, properly handled and tracked until they were properly resolved or stable. Serious adverse events and unexpected events were reported to the ethics committee, competent authorities, sponsors and drug supervision and management departments in a timely manner according to the regulations. The main researchers regularly conduct a cumulative review of all adverse events, and if necessary, convene a meeting of researchers to assess the risks and benefits of the study ; research that is greater than the minimum risk will arrange independent data monitors to monitor the research data, and high-risk research will establish an independent data security supervisory committee to monitor the accumulated security data and effectiveness data to make recommendations on whether the research will continue.

十、Statistical processing

All statistical analyses were performed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Categorical variables, including intubation success rate,

incidence of local airway trauma, extubation failure due to airway injury, and resident satisfaction rate, were expressed as counts and percentages [n (%)], and were compared between groups using the chi-square test (χ^2 test) or Fisher's exact test, as appropriate. Continuous variables, such as intubation completion time, were tested for normality using the Shapiro–Wilk test. Variables not conforming to a normal distribution were expressed as median (interquartile range) and compared using the Mann–Whitney U test. A two-tailed P value < 0.05 was considered statistically significant.

十一、Ethics in clinical research

Clinical research will follow the World Medical Congress ' Helsinki Declaration ' and other relevant provisions. Before the study began, the clinical study was carried out after the ethics committee approved the test plan. Before each subject is selected for this study, the researcher has the responsibility to fully and comprehensively introduce the purpose, procedure and possible risks of this study to the subjects or their agents, and to sign a written informed consent form. The subjects should be informed that they have the right to withdraw from the study at any time. Informed consent should be retained as a clinical research document for review. The personal privacy and data confidentiality of the subjects will be protected during the study.

十二、Research progress

1. Preparation Phase (September 2024)

• Finalization of study protocol, ethics committee approval, and trial registration.

• Recruitment of eligible emergency medicine residents.

• Baseline data collection and pre-intervention training using traditional methods.

2. Implementation Phase (October 2024 to September 2025)

- Full implementation of the PDCA cycle-based training program.
- Residents rotate through didactic sessions, simulation training, and supervised clinical practice.
- Continuous data collection on intubation performance, adverse events, and resident feedback.

3. Evaluation Phase (September 2025)

- Completion of data collection for both control and intervention groups.
- Statistical analysis of primary and secondary outcomes.
- Compilation of results for publication and dissemination.

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