Analysis of Breath Sounds During Surgery

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1. Background and Rationale

Auscultation is the practice of listening to physiological sounds using the ear or a stethoscope to assess cardiac and respiratory function. Conventional auscultation during anesthesia relies heavily on anesthesiologists' experience and is subjective, intermittent, and vulnerable to noise and surgical constraints.

Prior studies have shown that breath-sound–based monitoring may provide useful information on airway patency, ventilatory adequacy, and endotracheal tube positioning. However, the lack of continuous, objective, and standardized intraoperative breath sound monitoring limits timely detection of abnormal respiratory conditions.

Electronic stethoscope patches enable continuous, high-fidelity waveform capture and signal processing. Despite promising technology, large real-world intraoperative datasets remain scarce. This study aims to systematically collect breath sound waveforms and clinical respiratory events during general anesthesia to evaluate feasibility, accuracy, and potential clinical applications.

2. Study Objectives

Primary Objective:

- Evaluate the accuracy and agreement of breath-sound–based respiratory monitoring compared with clinical respiratory assessment.

Secondary Objectives:

- Analyze the correlation between acoustic features and intraoperative respiratory events.
- Explore feasibility and interpretability of real-time spectrograms and waveform characteristics for respiratory assessment.
- Evaluate user experience and workflow impact using a structured 5-point Likert scale.

- Develop and test signal-processing algorithms for identifying abnormal acoustic patterns (e.g., wheeze-like signals, amplitude reduction, spectral shift).

3. Study Design

This is a single-center, prospective, observational study conducted in operating rooms at Taipei Veterans General Hospital. Approximately 30 adult patients undergoing elective surgery under general anesthesia will be enrolled. This study does not involve randomization or blinding. Breath sound monitoring is non-invasive and observational; all anesthetic and surgical procedures follow standard clinical practice.

4. Study Procedures and Methods

4.1 Study Flow

1. Informed consent obtained preoperatively.
2. Routine physiologic monitors applied before induction.
3. Adhesive electronic stethoscope patches placed on the chest wall for baseline recordings.
4. General anesthesia induction, intubation, and surgery performed per standard care.
5. Continuous breath sound waveform collection throughout anesthesia (from induction to emergence).
6. Documentation of ventilator settings, clinical respiratory observations, and predefined respiratory events.
7. Removal of sensors at the end of surgery; patient transferred to recovery room.
8. Data extraction and offline analysis.

4.2 Device Placement

Two to four adhesive electronic stethoscope patches will be placed at the following predefined anatomical locations:

- Left 2nd intercostal space
- Right 2nd intercostal space
- Left anterior axillary line at the 5th intercostal space
- Right anterior axillary line at the 5th intercostal space

4.3 Data Acquisition

- Sampling rate: 8 kHz
- Format: raw waveform files (.wav) and exported .csv files
- Continuous recording from induction until emergence

4.4 Clinical Event Logging

Documented by anesthesiologists:

- Hypoventilation
- Airway obstruction
- Increased airway pressure
- Wheeze-like acoustic patterns
- Secretion accumulation requiring suction
- Endotracheal tube dislodgement/repositioning

4.5 Clinical Observations

Routine anesthetic and surgical care. If the sensor detaches, it will be repositioned. No intervention is dictated by study protocol.

5. Eligibility Criteria

Inclusion Criteria:

- Age ≥ 20 years
- ASA physical status I–III

- Scheduled for elective surgery requiring general anesthesia
- Able and willing to provide informed consent

Exclusion Criteria:

- Severe chronic pulmonary disease
- Severe chest wall deformity
- Skin allergy to adhesives or damaged skin at patch location
- Refusal or inability to participate

6. Outcome Measures

Primary Outcome Measure:

1. Accuracy of electronic breath sound monitoring during surgery

   Assessment will be based on the proportion of intraoperative respiratory events correctly identified by the electronic breath sound monitoring system compared with standard clinical assessment.

   Time Frame: During surgery (from induction of anesthesia until emergence)

Secondary Outcome Measures:

2. Incidence of respiratory events detected by the device

   Number of intraoperative respiratory events (e.g., hypoventilation, airway obstruction, disconnection) identified by the monitoring system.

   Time Frame: Intraoperative period

3. Correlation between electronic breath sound monitoring and clinical observation

   Correlation (r-value) between device output and anesthesiologist-documented respiratory findings.

   Time Frame: Intraoperative period

4. Feasibility of device use during anesthesia

Feasibility will be assessed by reporting the proportion of cases in which continuous breath sound monitoring was successfully completed without interruption, including documentation of signal quality issues and workflow interference if present.

(No rating scale will be used.)

Time Frame: Postoperative evaluation (immediately after surgery)

7. Sample Size Justification

A total of 30 subjects is sufficient for feasibility, pilot signal characterization, algorithm development, and effect-size estimation for future powered studies. This sample size is consistent with similar pilot studies on electronic auscultation and perioperative respiratory monitoring.

8. Statistical Analysis Plan (SAP)

8.1 Signal Processing

- Bandpass filtering (100–2000 Hz)
- FFT-based spectral analysis
- Spectrogram generation (Short-Time Fourier Transform)
- Extraction of power, amplitude, frequency peaks, and spectral ratios

8.2 Event Detection Performance

- Sensitivity, specificity, PPV, NPV
- ROC curves and AUC
- Confusion matrix comparing algorithm detection vs. clinician assessment

8.3 Agreement Analysis

- Bland–Altman analysis comparing acoustic-derived respiratory metrics with clinical reference values

8.4 Correlation and Paired Tests

- Spearman correlation between acoustic features and ventilatory parameters
- Paired t-test and Wilcoxon signed-rank test for within-subject comparisons

All analyses performed using validated statistical packages in Python or R.

9. Adverse Event Management

No adverse events are expected. Adhesive patches are non-invasive and pose minimal risk. If discomfort occurs, subjects may contact the provided 24-hour emergency number. Clinical evaluation will be arranged if needed. Participants may withdraw at any time without affecting their medical care.

10. Subject Rights and Safety Protections

Participants are protected under institutional and national human-subject research policies. Informed consent will be obtained from all participants. All collected data will be de-identified. Only authorized research personnel may access raw data.

11. Data Management and IPD Sharing

Breath sound waveforms and annotations will be stored securely on institutional servers. De-identified datasets may be shared upon request beginning 6 months after study completion. No identifiable information will be released.

12. References

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