Annals of Trauma & Acute Care

Research Article
Published: 20 Sep, 2021

Development of Clinical Device for Detecting Out-of-Hospital Traumatic Pneumothorax: Validation Using a Simulation Model in an Anechoic Chamber

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Abstract

Aim: Traumatic pneumothorax is highly common among patients with chest injury; however, its early detection can be challenging in noisy environments. We have previously developed a novel device with microphones attached to the stethoscope for detecting pneumothorax without human hearing. In this study, we aimed to evaluate the usefulness of our newly improved device with microphones and a noise canceling system for detecting pneumothorax in noisy environments.

Methods: The device was applied to a simulator mannequin set up under conditions of pneumothorax or normal control. Pink noise and traffic noise were used as a loud environment presumptively and emitted from a speaker.

Results: The device could detect pneumothorax even in loud environments with a noise of over 70 dB. The best noise-suppression effect was recorded at frequencies of 386 Hz to 398 Hz.

Conclusion: The newly improved device can accurately detect traumatic pneumothorax even in noisy environments and can thus be used as a diagnostic modality in the prehospital or disaster setting.

Keywords: Noise reduction; Pneumothorax; Sound analysis; Stethoscope; System identification

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Received Date: *16 Aug 2021*
Accepted Date: *15 Sep 2021*
Published Date: *20 Sep 2021*

Citation:
Hayashi N, Nakamura Y, Inoue Y, Tanaka H. Development of Clinical Device for Detecting Out-of-Hospital Traumatic Pneumothorax: Validation Using a Simulation Model in an Anechoic Chamber. Ann Trauma Acute Care. 2021; 5(2): 1028.

Introduction

Emergency medical staff is often dispatched to the field using cars or helicopters. In Japan, ambulances and helicopters are commonly used [1-3]. The emergency response team requires exceptional skills and experience because of the significant limitations in medical resources in the prehospital environment [4].

Traumatic pneumothorax is among the most common conditions that occur after a chest trauma. It can also occur from incorrect chest compressions that result to lung collapse. Pneumothorax is suspected or diagnosed based on the absence or attenuation of the ipsilateral lung sound. Subcutaneous emphysema on palpation is a standard diagnostic factor, but it is difficult to detect in cases of minor pneumothorax. Chest-radiography also has a low diagnostic capability, and occult pneumothorax is difficult to detect [5,6]. Chest Computed Tomography (CT) is the standard diagnostic modality for traumatic pneumothorax. However, CT is not available in the field. Field ultrasonography has been reported recently to be useful for the easy detection of pneumothorax, but its accuracy is highly influenced by the patient's obesity status and the technique of the physician [7].

Tension pneumothorax is characterized by increasing respiratory distress or difficulty ventilating with a BVM device, decreasing or absent breath sounds, and hemodynamic compromise. Patients with tension pneumothorax require emergency thoracotomy the soonest time possible. Thus, it is important to immediately and accurately determine the need for invasive chest drainage based only on physical examination [8,9]. We have previously developed a pneumothorax detection device that can record respiratory sounds and display them on a computer screen [10]. The device is attached to a commercially available stethoscope fitted with microphones and to a laptop. It can depict respirations as wave forms that can in turn be used to detect changes in respiratory pressure, particularly on the affected side. At a cutoff value of 8 dB in the difference in the sound pressure level between the normal and affected side, the device showed a sensitivity and specificity of 71.4% and 100% for detecting pneumothorax, respectively [11,12].

However, we encountered several problems with the device when it was used in the real world, particularly in loud environments such as in the pre-hospital setting of traffic accidents or inside a medical helicopter. This indicated that our device needs to be improved for clinical application. We hypothesized that fitting our previous device with a noise canceling technology used in commercially available headphones and microphones would improve its usefulness in a noisy environment [13]. The objective of this preliminary study for practical use was to evaluate whether the newly improved device can detect pneumothorax even in a loud environment.

Materials and Methods

Sound-collecting device

The previous system was composed of two sets of stethoscopes (Littman Cardiology III, 3M, St. Paul, MN) connected to a conductor microphone (ECM-C10, SONY, Tokyo, Japan). A noise-canceling device, developed by a specialized acoustic technology company (ARI Co., Ltd., Tokyo, Japan), was added in the microphone to cut the noise and detect acoustic changes in the public environment. In the newly improved device, microphones for ambient noise were added to each chest piece. Four inputs were entered through microphone amplifiers and an audio interface to a personal computer (Figure 1a). In the exclusive software, we can obtain a signal after noise cancelation from two inputs. One microphone collects the surrounding noise as a reference signal, while the other microphone collects sounds from the thoracic cage, which involves the lung sound passing through the thorax. This noise passing through the thorax includes altered components of the thoracic pathway. The device can eliminate the parameters associated with surrounding noise from processing sounds passing through the chest wall (Figure 1b).

This noise suppression method is based on system identification used in control engineering. We used Fast H∞ Filter (United States patent No.7039567, JST), a company-owned patented technology, as an adaptive filter. This technology has an algorithm that maintains the calculation volume within proper bounds and has good identification performance [14]. Quantization was performed at 16 bits and 48 kHz using the device.

Simulator

A simulator doll (Sim Man TM ALS, Laerdal Medical, Tokyo, Japan) whose bilateral respiratory sound levels were changed arbitrarily into the anechoic chamber was used to simulate an artificial pneumothorax condition. Respiratory motion and sound can be concurrently regulated in this simulator using a computer. Briefly, the left and right lung sound can be adjusted separately using a computer control dial, and unilateral pneumothorax can be simulated. The simulator was set up in a dedicated silent room (Figures 1c-1e).

Acoustic frequency analysis

Left pneumothorax was first simulated, and the detection thresholds were assessed to measure the frequency analysis. Sound data were analyzed using dedicated frequency software (Real time Analyzer TM version 5, Yoshimasa Electronic, Tokyo, Japan) capable of extracting sound pressure levels at a specific frequency. The Sound Pressure Levels (SPLs) of the inhalation peak time point were measured five times. The values were then added and averaged. Subsequently, the difference between the bilateral averaged SPLs was calculated (Figure 2). The cutoff value for positive pneumothorax was set at 8 dB based on our previous study [11,12].

The acoustic frequency was also measured for pneumothorax under two types of ambient noise: Pink noise and traffic noise, which was recorded on a real traffic road on the metropolitan main road. All noise samples were adjusted to 60, 70, 80, and 90 dB for pink noise and approximately 75 dB to 80 dB for traffic noise. The speaker that emitted noise sample was located 1 m away from the simulator doll, and the sound-level meter was set up 35 cm above the doll's chest wall (Figure 1c, 1d). These technical settings were based on those of our previous study [12]. These experiments were conducted on April 23rd and May 26th, 2015 in an anechoic chamber in Hachioji, Tokyo. All settings are listed in Table 1 of the Supplementary.

Statistical analysis

We used Fisher's exact tests to compare the categorical variables between two groups. All statistical analyses were conducted using Bell Curve for Excel (version 2.12; Social Survey Research Information, Tokyo, Japan), and $p<0.05$ was considered statistically significant.

Results and Discussion

The device performed well detecting pneumothorax in the anechoic chamber. We added up around 370 times of records. We set up various conditions with this mannequin, such as bilateral sound volume, vital signs (respiratory rate and heart rate), and additional noise (data not shown) and measure with or without NR (Table 1). The horizontal and longitudinal axes in Figure 3 show the frequency value and the accuracy, respectively. The device detected pneumothorax within a frequency band of 300 Hz to 400 Hz. A significantly different effect was obtained at 211 Hz and 234 Hz to 398 Hz with and without noise reduction ($p=0.036$ at 211 Hz, $p=0.010$ at 234 Hz and $p<0.001$ at 246, 258, 270, 281, 293, 305, 316, 328, 340, 352, 363, 375, 387, 398 Hz).

Figure 4 shows the effects of noise canceling on the noise patterns. The accuracy of the device under each frequency is shown only in under pink noise conditions (Figure 4a). A significant difference in pink noise detection was observed over 350 Hz, especially at 387 Hz. As for the traffic noise (Figure 4b), significant noise suppression was confirmed around 398 Hz. Figure 5 shows the accuracy of the noise canceling system for detecting pneumothorax under artificial noise conditions. Based on the previous result shown in Figure 4, we chose 387 Hz pink noise (Figure 5a) and 398 Hz traffic noise (Figure 5b) to demonstrate the optimal condition for the noise canceling system. The noise canceling system effectively cancelled pink noise as it increased, especially at over 70 dB. As for traffic noise, we confirmed a good noise-suppression effect of over 75 dB.

Figure 6 shows the device accuracy and difference between the respiratory sound levels of the simulator. A difference of zero means normal control, that is, no pneumothorax, and an increasing difference indicates worsening pneumothorax. Our device could detect pneumothorax with noise reduction if the difference between the left and right respiratory sound levels was at least 3. However, From 67% to 100 % decreased from 50% to 67% in the accuracy for pneumothorax detection when there was no noise reduction, even if the difference in sound level was the same.

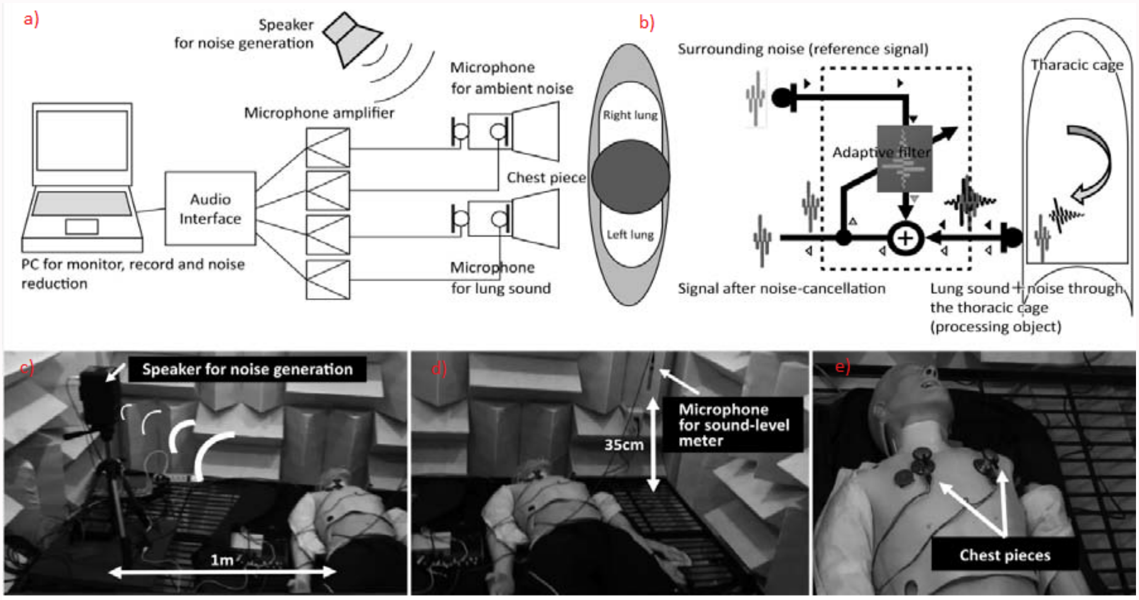

Figure 1: Experimental landscape and schematic illustration of the newly improved device.
a) Schematic illustration of the newly improved device. Microphones for ambient noise were added to each chest piece. Signal processing for the noise reduction was performed using patented software.
PC: Personal Computer; Audio Interface: Audio box 44VSL, Presonus, Baton Rouge, LA
b) A schematic diagram of system identification in the new software. A modified fast H infinity filter, which is an adaptive filter for system identification, as used. This system outputs a signal after noise cancelation from two inputs. One microphone collects the surrounding noise as a reference signal, and the other microphone collects sounds from the thoracic cage, which involves the lung sound and noise passing through the thorax.
This noise passing through the thorax includes altered components of the thoracic pathway. This device can eliminate parameters associated with time and surrounding noise from the processing object.
c-e) Simulator with our newly improved device in the anechoic chamber and experimental landscape. e) In this simulator, the lung sounds at each side of the lung can be controlled separately, allowing us to create a unilateral model of pneumothorax. Two sets of chest pieces were placed on the bilateral chest wall. c) The speaker for noise generation was set up 1 m away from the simulator, d) and the sound-level meter was located 35cm above the simulator's chest. Two types of noise samples are emitted from the speaker.

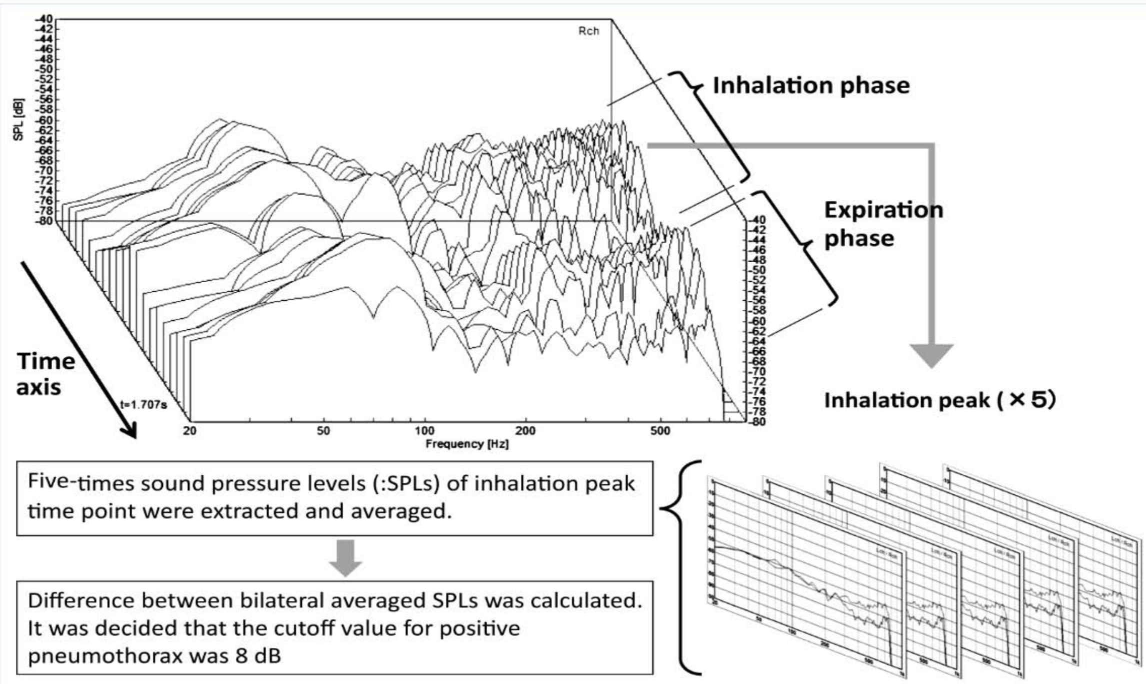

Figure 2: Acoustic analysis system.
Raw wave data recorded from the microphones were analyzed using dedicated computed software. First, five sound pressure levels at the inhalation peak time point were extracted and averaged. Subsequently, the difference between the bilateral averaged SPLs was calculated. The cutoff value for positive pneumothorax was calculated to be 8 dB based on our previous study.
SPLs: Sound Pressure Levels.

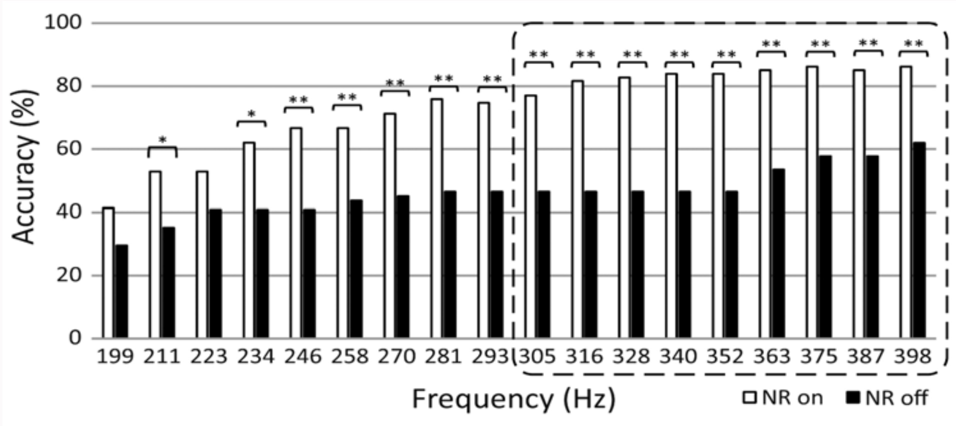

Figure 3: Accuracy of pneumothorax detection according to the acoustic sound frequency of respiratory sound.
The graph shows the relationship between the accuracy and acoustic sound frequency of respiratory sound. These data were recorded under the variable conditions of bilateral respiratory sound levels, respiratory rate, heart rate, and ambient noise level. The X-axis shows the frequency value, and the Y-axis shows the accuracy. The open column involves a Noise Reduction (NR) setting, and the closed column involves no noise reduction. This newly improved device was useful for pneumothorax detection within a frequency band of 300 to 400 Hz (frame working with dashed line). Fisher's exact test showed a significant difference between those with and without NR at 211 Hz and 234 Hz to 398 Hz.
NR: Noise Reduction

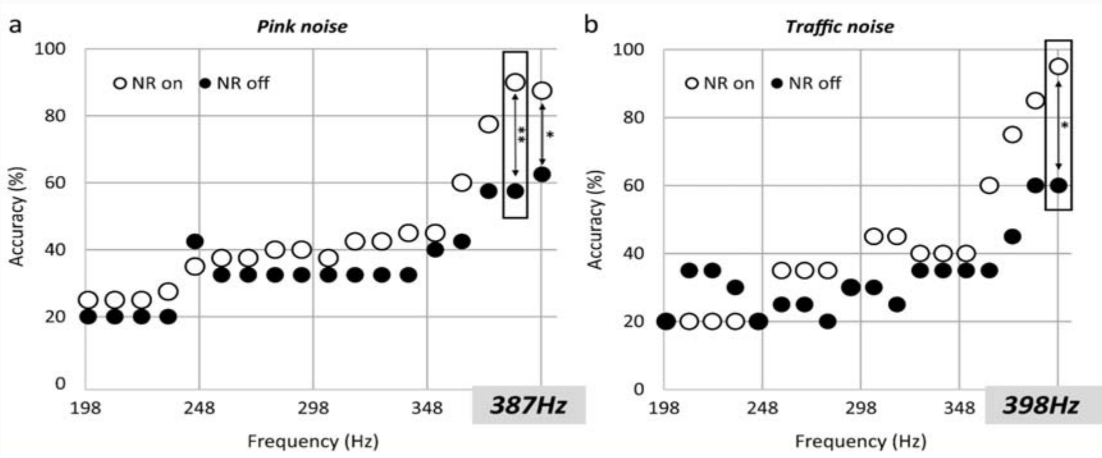

Figure 4: Device accuracy under two types of noise.
Device accuracy according to noise frequency under (a) pink noise and (b) traffic noise conditions. Open circles indicate noise reduction, and closed circles indicate noise reduction. Fisher's exact test showed significant differences in accuracy at 387 and 398 Hz under pink noise and at 398 Hz under traffic noise. The best effect for noise suppression was over 350 Hz. For pink noise and traffic noise, it was at 387 Hz and 398 Hz, respectively.

We have previously developed a novel device with microphones attached to the stethoscope for detecting pneumothorax in the field. In this study, we evaluated the usefulness of our newly improved device with microphones and a noise canceling system for detecting pneumothorax in noisy environments. The device showed good accuracy, detecting traumatic pneumothorax even in simulated noisy environments.

Thoracic trauma is a significant cause of mortality, with a high proportion of thoracic trauma patients dying after hospital admission. However, many of these deaths can be prevented with prompt diagnosis and timely and appropriate intervention [8,9,15]. Traumatic pneumothorax should be detected based on physical signs and/or plain X-ray films during primary and secondary surveys. However, these findings alone may be inadequate for achieving an accurate diagnosis. In particular, occult pneumothorax, a type of traumatic pneumothorax, can progress to life-threatening tension pneumothorax [5,6,16]. However, occult pneumothorax is only detectable on CT.

We have previously designed a record analysis device that presents changes in the pressure of respiratory sounds as wave forms [11,12]. This device can be used to detect pneumothorax in the Emergency Department (ED). However, it had problems with isolating and collecting respiratory sounds in a noisy environment, such as in accident scenes. Thus, it might be limited usefulness when used inside ambulances or medical helicopters. As such, a new device with noise-cancelling features and with the capability to differentiate between breath sounds in the normal and affected lung is needed.

In this study, the improved device accurately detected occult pneumothorax with a good noise-suppression effect. Further, the detection capability was independent of the influence of the respiratory and heart rates, as confirmed using a pneumothorax model in a simulator mannequin. To determine whether the device can isolate distracting sounds in a loud environment, we prepared two sets of noise samples as ambient noise: Traffic sounds and pink

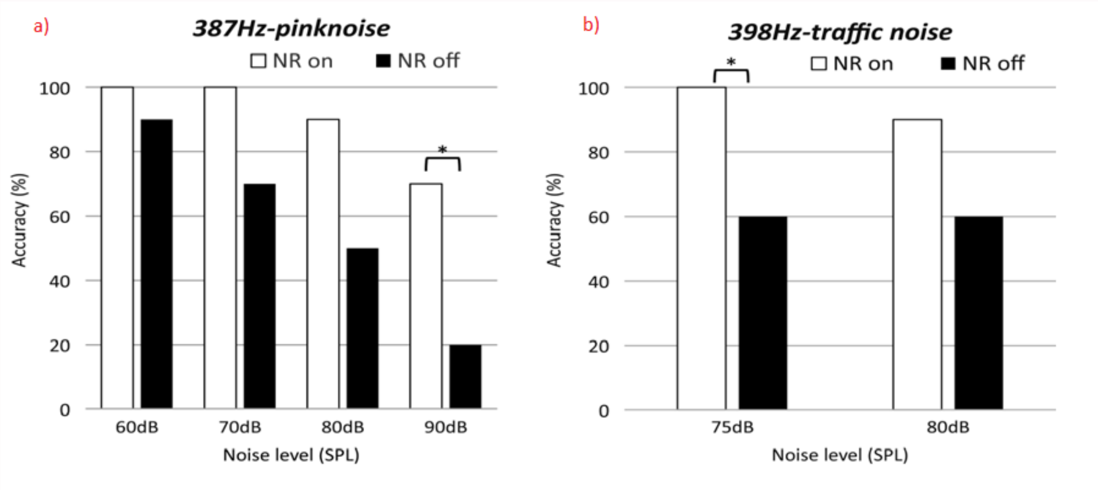

Figure 5: Accuracy at the highest frequency of pink and traffic noise.
A good noise-suppression effect was observed even in a loud environment of over 70 dB. (a) Fisher's exact test showed a significant difference at 387 Hz under a 90 dB pink noise level and (b) at 398 Hz under a 75 dB traffic noise level.
NR: Noise Reduction; SPL: Sound Pressure Level

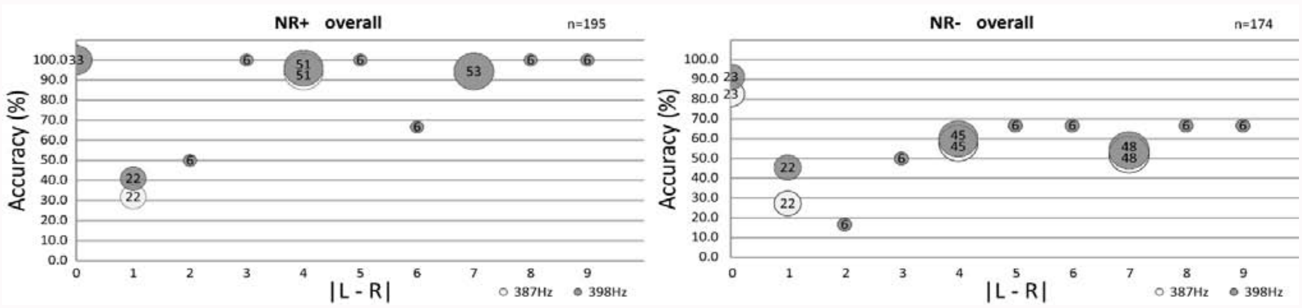

Figure 6: Accuracy and the difference in the simulator's respiratory sound levels.
The cutoff level was set at 8 dB. A good noise reduction effect was observed at both frequencies. The X-axis shows the absolute value of the sound levels of the left minus right lung settings, where "0" is assumed as non-pneumothorax and"1,2,3, …,9" indicate pneumothorax and the attenuation of the affected respiratory sound was expanding. Meanwhile, the Y-axis shows each accuracy. The bubble size corresponds to the number of experiments.

noise. Pink noise is one of the most common signals in biological systems and has a frequency spectrum whose power spectral density is inversely proportional to the frequency of the signal. Since the energy of each band called the octave band is uniform, it is used for various acoustic measurements. Traffic noise was recorded to simulate noise during traffic accidents. Our device could distinguish the affected side in the mannequin under both traffic and pink noise conditions, indicating that it can be applicable not only at the ED, but also outside hospital settings.

The device performance was maintained even in a simulated outdoor environment with a noise of over 70 dB. Normal environments typically have a noise index of 70 dB, such as inside trains, in main streets, and outdoors [17,18]. When we evaluated the device accuracy based on the difference in the respiratory sound levels of the simulator <|L-R|>, our device could detect pneumothorax accurately if the difference in the left-right breath sounds was at least 3. However, the device could not detect pneumothorax when the difference was less than 3, indicating that it has limited usefulness in cases of minor pneumothorax. Moreover, the accuracy of our new device was significantly reduced at noise levels above 80 dB. We believe that this problem is caused by the surrounding noise having a sound spectrum similar to that of human lung sounds. The next step would be to improve the sensitivity at over 80 dB of noise.

Ultrasonography has been recently reported to be useful for detecting pneumothorax in the clinical setting [19-21]. And the teaching method for ultrasound diagnostics of pneumothorax using porcine models has been designed [22-24].

However, it requires experience and familiarity, especially when used in the field. Accordingly, our future research directions will involve combining the device with small ultrasonography machines and microphones in the stethoscope to detect even minor occult pneumothorax at noise levels of less than 80 dB. I will try to measure with humans and compare the accuracy with other devices.

The limitation of this study was that it was a simulated trial. It cannot be said that the actual traumatic pneumothorax could be reproduced, but at least from the viewpoint of detecting the laterality of breath sounds, it is argued that the device is useful in a noisy environment. Clinical trials are needed to verify the usefulness in noisy environments. Jang-Zern reported that human body has left-right asymmetry in spectral characteristics in lung sounds [25]. We have to collect human standard as well. Another limitation was vibrational problem [26]. It has a profound effect on the auscultation when the helicopter's engine is cranked-up. These problems are our issues in the future. And these measurements and statistical processing were all done by ourselves, so they are not blind tests. I think this is a big bias.

Conclusion

In conclusion, our newly improved device had a good noise-suppression effect even in a simulated loud environment of over 70 dB. Thus, it may be useful as a noninvasive diagnostic tool for detecting pneumothorax in prehospital settings.

Acknowledgment

We thank Katsuaki Satoh and Amenity Research Institute (ARI) for his technical advice and the provision of the company's anechoic chamber. This work was supported by the Ministry of Education, Culture, Sports, Science and Technology (KAKENHI) [Grant Number: JP25861734], Grant-in-Aid for Young Scientists (B), 2013-2016. Part of this research was presented at the 29th Annual Meeting of the Japanese Association for the Surgery of Trauma.

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