ORIGINAL ARTICLE

A prospective study: Is handheld micropower impulse radar technology (Pneumoscan) a promising method to detect pneumothorax?

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ABSTRACT

BACKGROUND: This study aimed to discuss the effectiveness of Pneumoscan working with micropower impulse radar (MIR) technology in diagnosing pneumothorax (PTX) in the emergency department.

METHODS: Patients with suspicion of PTX and indication for thorax tomography (CT) were included into the study. Findings of the Thorax CT were compared with the results of Pneumoscan. Chi-square and Fisher's exact tests were used in categorical variables.

RESULTS: One hundred and fifteen patients were included into the study group; twelve patients presented with PTX diagnosed by CT, 10 of which were detected by Pneumoscan. Thirty-six true negative results, sixty-seven false positive results, and two false negative results were obtained, which resulted in an overall sensitivity of 83.3%, specificity of 35.0% for Pneumoscan. There was no statistically significant difference between the effectiveness of Pneumoscan and CT on the detection of PTX (p=0.33). There was no difference between the size of PTX diagnosed by CT and PTX diagnosed by Pneumoscan (p=0.47). There was no statistically significant difference between Pneumoscan and CT on detecting the localisation of the PTX (p=1.00). For the 10 cases diagnosed by Pneumoscan, mean chest wall thickness was determined as 50.3 mm while mean chest wall thickness for two false negatives diagnosed by Pneumoscan was 56.5 mm. However, no statistically significant difference was found between the chest wall thickness and the effectiveness of Pneumoscan on the detection of the PTX (p=0.77). Among sixty-seven false positives diagnosed by Pneumoscan, 46.3% had additional medical signs such as bronchiectasis, pulmonary consolidation, pulmonary edema or pulmonary tumor when they had a reading with CT. The relationship between having additional medical signs at the reading with CT and the effectiveness of Pneumoscan on the detection of the PTX was investigated and no significant difference was found (p=0.472).

CONCLUSION: Using Pneumoscan to detect PTX is controversial since the device has a high false positive ratio. Wherein, false positive diagnosis can cause unjustifiable chest tube insertion. In addition, the device failed to show the size of the PTX, and therefore, it did not aid in determining the treatment and prognosis on contrary to traditional diagnostic methods. The findings could not demonstrate that the device was efficient in emergency care. Further studies and increasing experience may change this outcome in upcoming years.

Keywords: Micropower impulse radar technology; Pneumoscan; pneumothorax.

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INTRODUCTION

Pneumothorax (PTX) is defined as air in the pleural space between the parietal and visceral pleura.[1] In the US, the rate of primary spontaneous PTX is reported as 7.4 and the rate of secondary spontaneous PTX is reported as 8.3 per 100.000 person per year.[1] It has been reported that about 25% of trauma-related deaths are caused by thoracic injury. Pneumothorax is one of the common manifestations and preventable causes of death of thoracic injury.[2]

Small and medium pneumothorax is not a potentially life threatening condition; however, tension pneumothorax is often preceded by small and medium pneumothorax. Therefore, early diagnosis and treatment of small and medium pneumothorax is important to prevent its progression to tension pneumothorax.[3]

Since pneumothorax is a commonly encountered life threatening condition in the emergency department (ED), prompt identification and treatment of traumatic pneumothorax are an imperative part of emergency care for chest trauma patients.[4] However, it can be difficult to detect PTX.

In order to diagnose PTX, patients who are at high risk for PTX should be carefully examined; however, it should be noted that clinical examination is true positive in only 60% of the patients.[5] This situation makes diagnostic imaging modalities imperative.[6] Portable chest radiography (CXR), computed tomography (CT scan) and, Ultrasonography (US) are the recommended diagnostic imaging modalities.[5] It has been stated that CT provides higher degree of accuracy on determining PTX than other recommended diagnostic imaging modalities.[5] However, CT has a few major drawbacks like high doses of radiation, cost, and longer time. Especially, high dose of radiation can be really harmful for the patient and the personnel in charge of the patient.[7,8]

Recent research has focused on new technologies that are robust, fast, cheap, and simple to handle, portable, accurate, reliable, and available for preclinical and clinical settings.[6,9] Considering these purposes, several devices have been developed.

The aim of this study was to assess the effectiveness of Pneumoscan that utilizes micropower impulse radar (MIR) technology on the diagnosis of PTX which can be a life threatening condition unless diagnosed early.

MATERIALS AND METHODS

This is a prospective study approved by the Evaluation of Scientific Research Committee. This study was conducted in the emergency department of Dr. Lütfi Kirdar Kartal Training and Research Hospital between November 2012 and April 2013. On average, about 800 injured patients are treated in the emergency department per day.

Pneumoscan Device

The Pneumoscan device used in this study has been manufactured as a handheld pneumothorax detector. This device works with MIR technology and is used for the diagnosis of PTX when other diagnostic devices are not available (Fig. 1a).[9]

Since current methods of PTX detection are not practical for pre-hospital providers or battlefield medics, a novel device based on MIR technology has been developed for the identification of PTX.[10]

The device works by emitting ultra-short radar pulses (<1 ns).[11] Ultra-short waves that can penetrate body cavities are reflected back from the body based on the relative permittivity of the structures. Different path of transmission properties of the tissues determines the size of the reflected waves. Since ultra-short waves are able to distinguish tissue types such as fat, muscle, bone, pooled blood from air and each other, this technology has been used to diagnose PTX.[12] Technological properties of this device produced for a non-invasive diagnosis of PTX have been improved by the manufacturers. The device used in this study has been produced by PneumoSonic Inc. (Cleveland, OH, USA) and has CE certificate (CE certificate 0086). The device spreads low-power ultrashort electromagnetic signals between 500 megahertz-6 gigahertz.[13] The device consists two parts including portable handheld computer (Fig. 1b) and MIR transceiver (Fig. 1c).

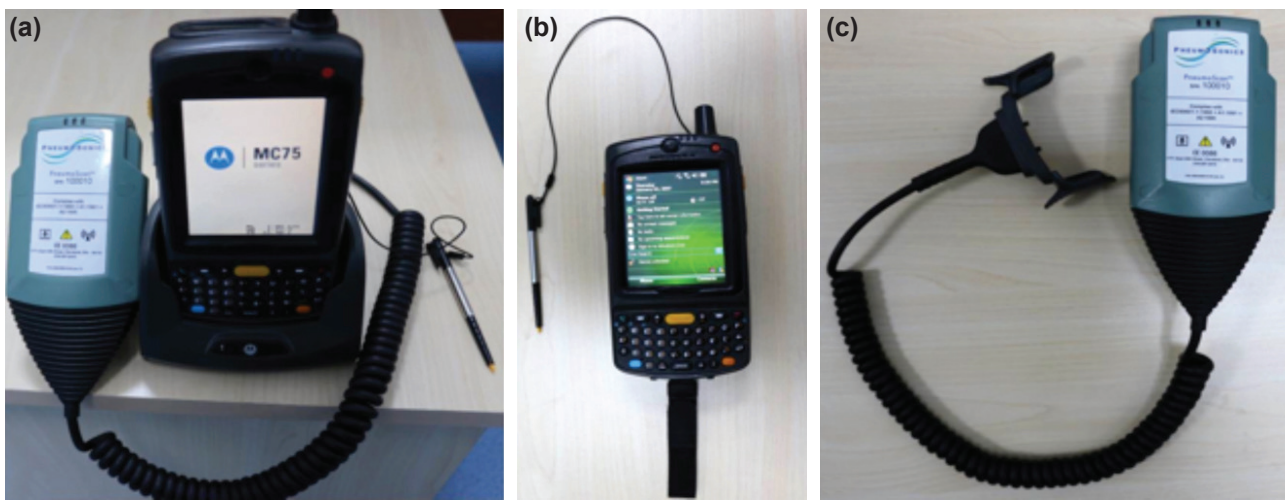

Figure 1. (a) Pneumoscan device. **(b)** Handheld computer. **(c)** MIR transceiver.

Handheld computer provides power to the probe and makes real time analysis of the incoming data from the probe. MIR transceiver spreads radar pulse to the tissues and sends signals to the control module. In this case, the system analyzes the impulses reflected from the body and detects PTX.

Use of the Device

The handheld computer displays eight scan locations so as to place the transceiver properly on the patients and the images are displayed as animated images. After placing the transceiver on the first scan location, analysis takes nearly a second, and then, the scanning proceeds to the other locations shown on the screen (Fig. 2). After completing the scan on eight locations, hand held computer analyzes the data. On the screen in animated image, green color displays no PTX and red displays PTX finding (Fig. 3).

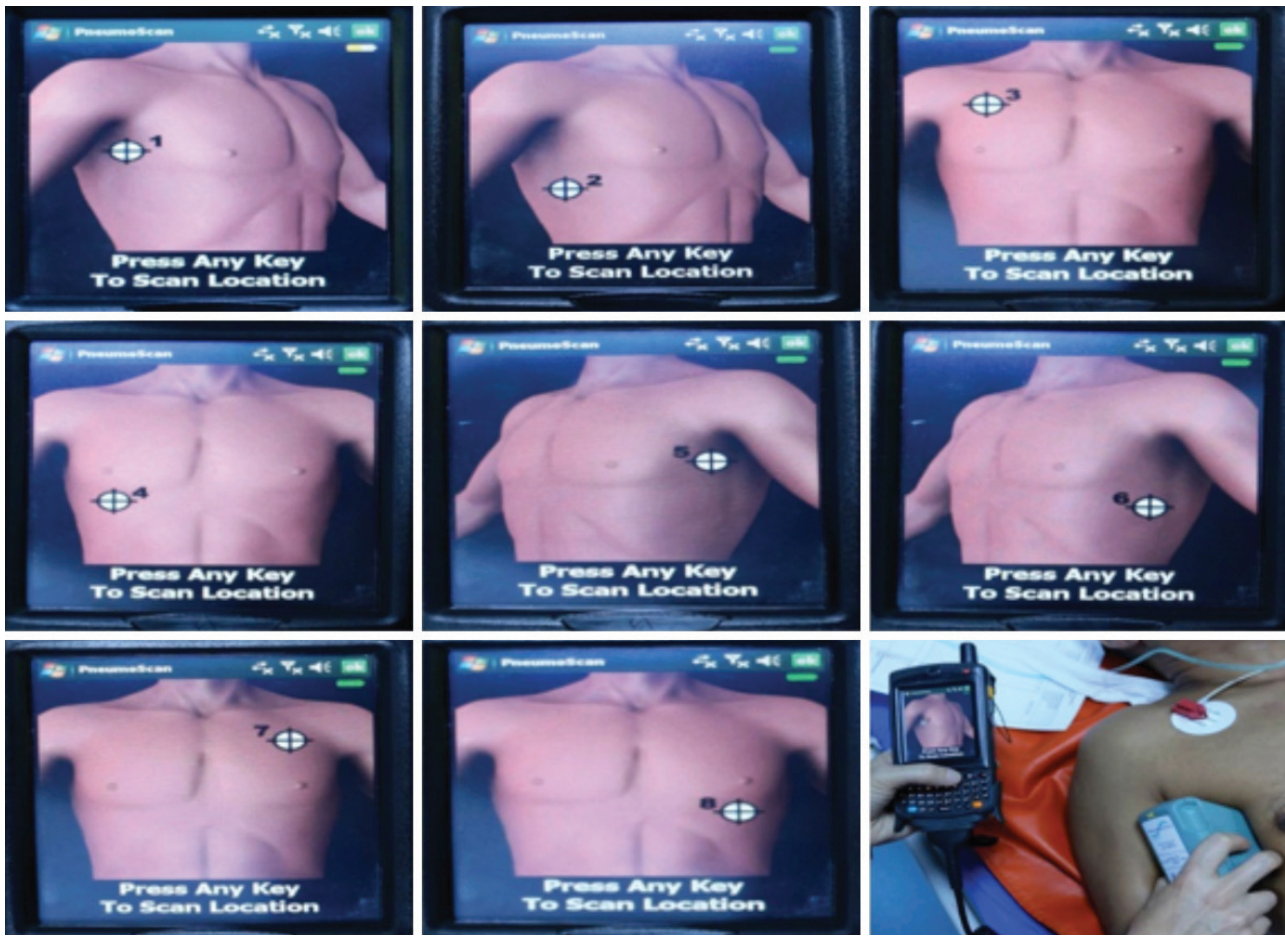

Figure 2. Pneumoscan data acquisition points and example of real-time Pneumoscan data interpretation and report.

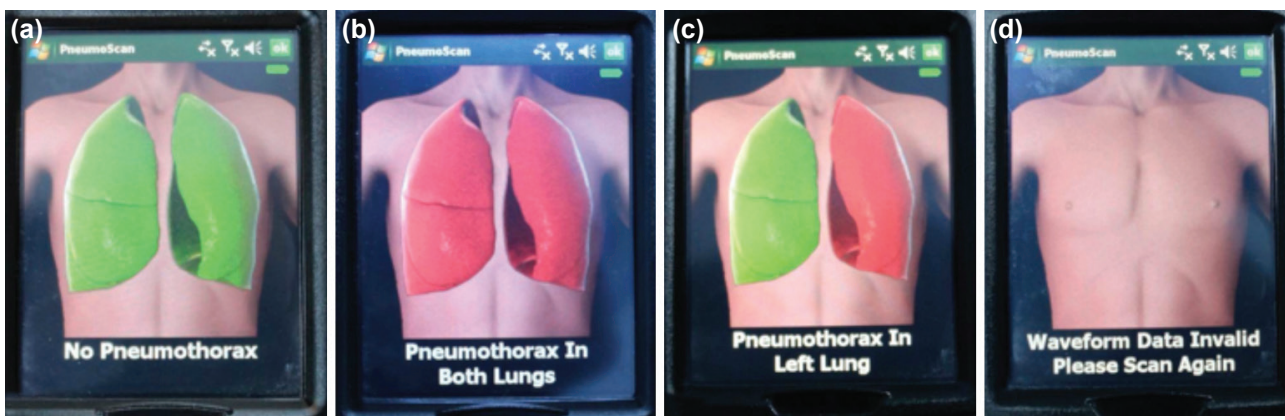

Figure 3. Display of results: Red = PTX, Green = no PTX. **(a)** No pneumothorax. **(b)** Pneumothorax in both lungs. **(c)** Pneumothorax in the left lung. **(d)** The device cannot analyze.

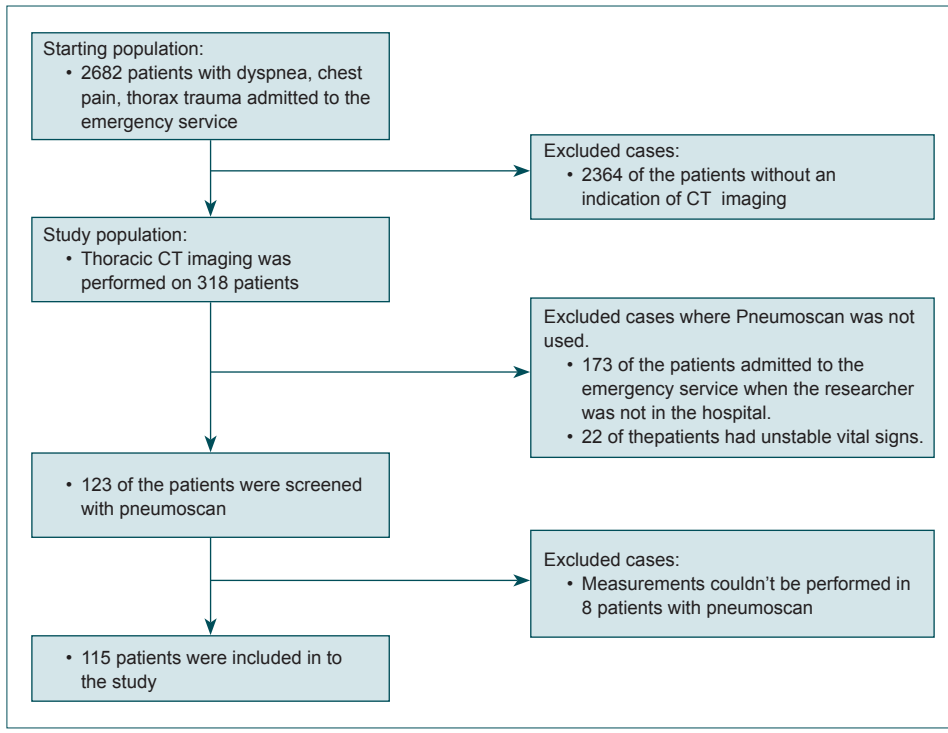

Figure 4. Flow diagram of the study population.

Study Procedure

Patients who complained about shortness of breath, chest pain, thoracic trauma and patients with a clinical suspicion of Pneumothorax and undergoing CT-scan were included into this study. Patients with tension pneumothorax and unstable patients were excluded from the study.

For the cases that the device could not perform an analysis, measurements were carried out consecutively up to four times. In case that the device could not perform an analysis at the fourth time, those cases were excluded from the study. Tomographically confirmed PTX cases were classified as described by the British Thoracic Society (BTS).[14] Study population and inclusion/exclusion flow chart are shown in Figure 4.

The assessment of the effectiveness of Pneumoscan on the diagnosis of PTX was carried out as follows;

True Positive Result: Patients diagnosed with PTX by both Pneumoscan and CT.

True Negative Result: Patients not diagnosed with PTX by both Pneumoscan and CT.

False Positive Result: Patients diagnosed with PTX by Pneumoscan but not by CT.

False Negative Result: Patients diagnosed with PTX by CT but not by Pneumoscan.

Statistical analysis was undertaken using the Statistical Package for Social Science (SPSS, v18.0, Chicago, IL). The Fisher's Exact test and Chi-square test were used for the comparison of the results of Pneumoscan to the true disease state revealed by CT. Statistical significance was taken as $p<0.05$.

RESULTS

Mean age of the patients included was 50.93 years (range, 14-97). 66.1% (n=76) of the patients were male and 33.9% (n=39) were female. 45.2% (n=52) of the patients were hospitalized for trauma, and 54.8% (n=63) for reasons other than trauma.

In this study, twelve patients presented with PTX were diagnosed by CT, 10 of which were detected by Pneumoscan. Thirty-six True Negative Results, sixty-seven False Positive Results, and two False Negative Results were obtained, which resulted in an overall sensitivity of 83.3%, specificity of 35.0% for Pneumoscan (Table 1).

There was no statistically significant difference between the effectiveness of Pneumoscan and CT on the detection of PTX (p=0.33). Among twelve cases presented with PTX diagnosed by CT, seven had PTX in the size of less than 2 cm and five had PTX in the size of more than 2 cm. There was no difference between the size of PTX diagnosed by CT and PTX diagnosed by Pneumoscan (p=0.47) (Table 2).

There was no statistically significant difference between

Table 1. Comparison of the results of pneumoscan and CT for pneumothorax

	Pneumothorax on computed tomography		Pneumothorax on computed tomography		Fisher's Exact Test p
	n	%	n	%	
Pneumothorax on Pneumoscan					
Present	10	83.3	67	65.0	0.33
Absent	2	16.7	36	35.0	
Total	12	100.0	45	43.7	

Table 2. Relationship between the size of pneumothorax and diagnosis with Pneumoscan

	Number of cases according to the size of pneumothorax on thorax computed tomography			
Pneumothorax on Pneumoscan	n (<2 cm)	n (>2 cm)	Total	Fisher's Exact Test p
Present	5	5	10	0.470
Absent	2	0	2	
Total	7	5	12	

Table 3. Mean chest wall thickness of the patients diagnosed with pneumothorax or not on Pneumoscan

Pneumothorax on Pneumoscan	n	Mean chest wall thickness of patients (mm)
Present	10	50.3000
Absent	2	56.5000

Table 4. The relationship between having additional signs on CT and the effectiveness of Pneumoscan on the detection of pneumothorax

	No sign on CT		Sign on CT				Chi-Square Test p
	n	%	n	%	n	%	
Pneumothorax on Pneumoscan							
Present	36	53.7	31	46.3	67	100.0	0.472
Absent	22	61.1	14	38.9	36	100.0	
Total	58	56.3	45	43.7	103	100.0	

CT: Computed tomography.

Pneumoscan and CT on detecting the localization of the PTX (p=1.00).

For the ten cases diagnosed by Pneumoscan, mean chest wall thickness was determined as 50.3 mm, while mean chest wall thickness for two false negatives diagnosed by Pneumoscan was 56.5 mm (Table 3). However, no statistically significant difference was found between chest wall thickness and the effectiveness of Pneumoscan on the detection of PTX (p=0.77).

Of the remaining one hundred and three patients without PTX, sixty-seven false positives were found by Pneumoscan, yielding an overall specificity of 35.0%. Among the sixtyseven false positives diagnosed by Pneumoscan, 46.3% had additional medical signs such as bronchiectasis, pulmonary con-

Table 5. Comparison of false positive, true negative pneumothorax diagnosed with Pneumoscan and having additional signs on computed tomography

	Pneumothorax on Pneumoscan				Total	
	Present		Absent			
Signs on computed tomography	n	%	n	%	n	%
Bronchiectasis	12	80.0	3	20.0	15	100.0
Consolidation	1	25.0	3	75.0	4	100.0
Fluid	13	68.4	6	31.6	19	100.0
Mass	5	71.4	2	28.6	7	100.0
Absent	36	62.1	22	37.9	58	100.0
Total	67	65.0	36	35.0	103	100.0

solidation, pulmonary edema or pulmonary tumor when they had a reading with CT (Table 4). The relationship between having additional medical signs at the reading with CT and the effectiveness of Pneumoscan on the detection of PTX was investigated and no significant difference was found (p=0.472) (Table 5).

Limitations

Having small number of patients and not specifying the study group as multiple trauma or thorax trauma were the limitations of this study.

DISCUSSION

A new handheld device, the Pneumoscan, using MIR technology has been recently produced, and it is still a developing technology for rapid detection of PTX. This device is considered to be superior to other methods since it does not spread radiation and is easy to use, and it can be used for trauma patients as well as in pre-hospital conditions.[15]

In our study, Pneumoscan had 83.3% sensitivity in the detection of PTX, but it was also found that this device had a high percentage (65%) in the detection of false positives.

Van der Wilden, Albers and Levy et al. have respectively reported 100%, 85.7%, and 100% specifity and 91.3%, 97.7%, 88.9% sensitivity in their studies.[9,10,16] The sensitivity in our study was 83.3%, which was relatively close to the one found by Albers et al. It was also detected that 34.9% specificity was quite a low specificity compared to other three studies.

In our study, it was found that among the one hundred and three patients who did not have PTX, sixty-three of them were diagnosed with false positive PTX by Pneumoscan. This was a remarkable and quite a different finding when compared to the other three studies conducted to assess the effectiveness of Pneumoscan on the detection of PTX.

The reasons for high rate of false positive diagnoses are thought to be related to the person who performed all readings, controlled the device and the patient. However, this device is designed to be independent of medical knowledge and usable by everyone.[9] Thus, the possibility of error depending on the person who performed Pneumoscan readings does not seem reasonable. In case the possibility of false positive diagnosis depends on device functioning, the company was frequently consulted with, and it assured that the device worked properly. In our study unlike other studies on this subject, we investigated whether the causes of false positives were other lung diseases such as bronchiectasis, consolidation, pleural effusion, and atelectasis and chest wall thickness; however, we did not find any significant relationship between the cause of false positives and the other lung diseases. The low specificity ratio found in our study contributes to the manufacturer in the developmental process of Pneumoscan.

The sensitivity of chest X-ray screening test, which is the primary radiological diagnosis of PTX, was 80%. Since performing chest X-ray for a patient with multiple organ injury is not possible, usually chest X-ray is taken when the patient is lying down. However, the sensitivity of direct diagnostic radiographs in hospitalized trauma patients is low.[5,17,18] Diagnostic sensitivities of anteroposterior radiographs which are made in the supine position have been found as 36–48%.[19] More than half of post-traumatic PTX may be overlooked.[5] Especially,evaluating patients, like multi-trauma patients, in supine position requires bedside and more sensitive devices than direct radiography. With the improvement in Pneumoscan technology, this could be a unique diagnostic device.

CT may not be always accessible and transportation of an unstable trauma patient to the tomography unit for CT includes risks.[5] Other disadvantages of CT include high-cost and high-dose radiation.[7,8] Ultrasonography (USG) is recommended for unstable patients unable to go to the tomography unit. It has been reported that the sensitivity of USG is higher

than the sensitivity of the radiographs.[5] The sensitivity of USG varies between 86–98% and specificity varies between 97–100%. With the increasing use of USG for hospitalized patients, it has become a common method for the diagnosis of pneumothorax. The low sensitivity of radiographs taken lying down shows that the use of the USG will be more common.[17,19] Some studies have shown that the sensitivity and specificity of USG is high for the diagnosis of occult pneumothorax in intensive care unit patients.[11]

This study investigated the effectiveness of this new technology on the detection of the PTX. Based on our findings, Pneumoscan had relatively high sensitivity; however, the specificity of this device was quite low. Using Pneumoscan to detect the PTX is controversial since the device has a high false positive ratio. Wherein, false positive diagnosis can cause unjustifiable chest tube insertion. Patients with large bulla may be evaluated as having pneumothorax and may cause a terrible complication unless enough experience has been obtained. In addition to that, this device is not able to assess the exact size of the PTX. Hence, it is thought that unlike conventional diagnostic imaging methods, Pneumoscan cannot be helpful in determining treatment and prognosis. The findings could not demonstrate that the device was efficient in emergency care. Further studies and increasing experience may change this outcome in upcoming years.

Conflict of interest: None declared.

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ORİJİNAL ÇALIŞMA - *ÖZET*

İleriye yönelik bir çalışma: Taşınabilir micropower impulse radar teknolojisi (Pneumoscan) pnömotoraks tanısında umut veren bir metot mudur?

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AMAÇ: Micropower impulse radar (MIR) teknolojisi ile çalışan Pneumoscan cihazının acil serviste pnömotoraks (PTX) tanısı koyabilmedeki etkinliğini değerlendirmeyi amaçladık.

GEREÇ VE YÖNTEM: Pnömotoraks şüphesi bulunan ve toraks bilgisayarlı tomografisi (BT) endikasyonu olan hastalar çalışmaya dahil edildi. Toraks tomografisindeki bulgular ile Pneumoscan cihazının sonuçları karşılaştırıldı. Katagorik değişkenlerin kıyaslanmasında ki-kare ve Fisher kesin testi kullanıldı.

BULGULAR: Çalışma grubunu oluşturan 115 hastanın toplam 12'sinde BT ile PTX tespit edildi. Pneumoscan'da 10 doğru pozitif sonuç, 36 doğru negatif sonuç, 67 yanlış pozitif sonuç, iki yanlış negatif sonuç vardı. Pneumoscan ile toraks BT'nin pnömotoraksı tespit edebilirliği arasında istatistiksel olarak anlamlı bir fark bulunmamıştır (p=0.33). Cihazın pnömotoraksı tespit etmedeki sensitivitesi %83.3, spesifitesi %35.0 olarak bulundu. Göğüs tomografisinde görülen pnömotoraksın boyutu ile cihazımızın pnömotoraksı belirlemesi arasında anlamlı bir farklılık bulunamamıştır (p=0.470). Bilgisayarlı tomografide PTX'lerin sağ ya da sol hemitoraksta olması ile cihazın pnömotoraksı tespit etmesi arasında anlamlı bir farklılık bulunamamıştır (p=1.00). Pneumoscan'ın doğru pozitif olarak tespit ettiği 10 hastanın, tomografide ölçülen göğüs duvar kalınlığı ortalama 50.3 mm iken, yanlış negatif iki hastanın göğüs duvar kalınlığı ise 56.5 mm olarak bulunmuştur. Ancak göğüs duvar kalınlığı ile cihazın tanı koyması arasındaki ilişki istatistiksel olarak anlamlı değildi (p=0.766). Pneumoscan'ın yanlış pozitif olarak PTX var dediği 67 olgunun %46.3'ünde (n=31) BT'de bronşiektazi, konsolidasyon, sıvı ve kitle gibi PTX dışı bulguları vardı. Tomografide ek bulgu olup olmaması ile cihazın pnömotoraks tespit edip etmesi arasında anlamlı bir farklılık bulunamamıştır (p=0.472).

TARTIŞMA: Çalışmamızla pnömotoraksı olan hastaları ayırt etme konusunda etkin olan Pneumoscan cihazının acil serviste kullanımı, yüksek yanlış pozitiflik oranından dolayı tartışmalı hale gelmiştir. Yanlış pozitif tanı oranındaki bu yükseklik bazı hastalara gereksiz chest tube takma girişimine neden olabilir. Ayrıca pnömotoraksın büyüklüğünü gösteremeyen Pneumoscan cihazı, geleneksel tanısal görüntüleme yöntemlerinin aksine verilecek tedaviyi ve prognozu belirlemede yardımcı olamamaktadır. Bulgular cihazın acil serviste kullanımının etkin olmadığını göstermiştir. İlerleyen yıllarda artan deneyim ve çalışmalar ile bu sonuç değişebilir.

Anahtar sözcükler: Micropower impuls radar teknolojisi; Pnomoscan; pnömotoraks.

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