

# Observing Pneumothoraces: The 35 Millimeter Rule is Safe in Ventilated Patients

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## ABSTRACT

**Background:** Observing pneumothoraces (PTXs) identified on chest computed tomography (CT) in mechanically ventilated patients remains highly debated. Despite the comorbidities associated with tube thoracotomy (TT), clinicians are inclined to perform this invasive procedure prophylactically. We hypothesize that PTX measuring  $\leq 35$  mm on chest CT can be safely observed in ventilated patients.

**Study design:** A retrospective review was conducted of all patients diagnosed with PTX by chest CT between January 2011 and December 2016. Patients were excluded if they had an associated hemothorax (HTX), were not intubated, or had a TT placed before the initial chest CT. PTXs were measured as the radial distance between the parietal and the visceral pleura/mediastinum in a line perpendicular to the chest wall on axial imaging. Based on the previous work, a cutoff of 35 mm on the initial CT was used to dichotomize the groups. Failure of observation was defined as the need for a TT during the first week. A univariate analysis was performed to identify predictors of failure of observation in both groups.

**Results:** A total of 116 patients met our inclusion criteria. Of those, 96 (83%) were successfully observed until discharge. Of those successfully observed, 88 (92%) patients had a measurement of  $\leq 35$  mm. In the univariate analyses, only the size of the PTX ( $\leq 35$  mm or  $> 35$  mm) ( $p = 0.001$ ) was significantly associated with failing observation. The negative predictive value for 35 mm as a cutoff was 96.7% to predict successful observation.

**Conclusion:** The 35 mm cutoff is safe as a general guide for ventilated patients with only 3% of stable patients failing initial observation.

**Keywords:** Chest tube, Observation, Pneumothorax, Pneumothoraces, Trauma.

*Panamerican Journal of Trauma, Critical Care & Emergency Surgery* (2019); 10.5005/jp-journals-10030-1234

## RESUMEN

**Antecedentes:** la observación de los neumotórax (PTX) identificados en la tomografía computarizada (TC) de tórax en pacientes con ventilación mecánica sigue siendo un gran debate. A pesar de las comorbilidades asociadas con la toracotomía con sonda (TT), los médicos están dispuestos a realizar este procedimiento invasivo de manera profiláctica. Nuestra hipótesis es que el PTX que mide  $\leq 35$  mm en la TC de tórax se puede observar de forma segura en pacientes ventilados.

**Diseño del estudio:** Se realizó una revisión retrospectiva de todos los pacientes diagnosticados con PTX por TC de tórax entre enero de 2011 y diciembre de 2016. Se excluyó a los pacientes si tenían una hemotórax asociado (HTX) no se intubó o se colocó un TT antes de la TC de tórax inicial. Las PTX se midieron como la distancia radial entre la pleura / mediastino parietal y visceral en una línea perpendicular a la pared torácica en la imagen axial. Sobre la base del trabajo anterior, se utilizó un corte de 35 mm en la TC inicial para dicotomizar los grupos. La falta de observación se definió como la necesidad de un TT durante la primera semana. Se realizó un análisis univariado para identificar los factores predictivos del fracaso de la observación en ambos grupos.

**Resultados:** Un total de 116 pacientes cumplieron con los criterios de inclusión. De ellos, 96 (83%) se observaron con éxito hasta el alta. De los observados con éxito, 88 (92%) pacientes tenían una medida de  $\leq 35$  mm. En los análisis univariados, solo el tamaño de el PTX ( $\leq 35$  mm o  $> 35$  mm) ( $p = 0,001$ ) se asoció significativamente con la observación fallida. El valor predictivo negativo de 35 mm como valor de corte fue del 96.7% para predecir la observación exitosa.

**Conclusión:** El valor de corte de 35 mm es seguro como una guía general para pacientes ventilados, con solo el 3% de los pacientes estables que no cumplen con la observación inicial.

**Palabras clave:** Neumotoráceas, Neumotórax, Observación, Trauma, Tubo torácico.

## INTRODUCTION

Computed tomography (CT) scan is a routine in the evaluation of trauma patients. As a result, physicians are frequently detecting minor abnormalities and incidental findings. As more pneumothoraces (PTXs) are detected,<sup>1</sup> more questions arise on the appropriate management of these patients. Traditionally, tube thoracostomy (TT) has been the mainstay of treatment for traumatic PTXs, especially in ventilated patients. However, as new evidence emerges, many clinicians now support observing clinically stable patients with PTXs.<sup>1-9</sup>

The first randomized controlled trial (RCT) to address observing patients with stable PTX was in 1993 by Enderson et al.; of the

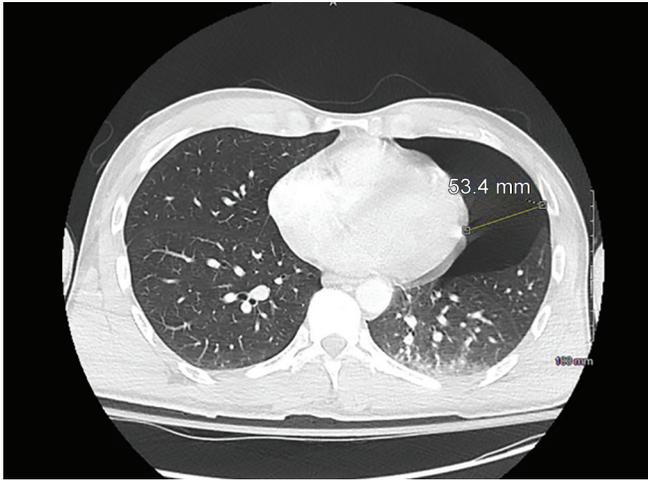
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**How to cite this article:** Eddine SBZ, Boyle KA, et al. Observing Pneumothoraces: The 35 Millimeter Rule is Safe in Ventilated Patients. *Panam J Trauma Crit Care Emerg Surg* 2019;8(1):29-35.

**Source of support:** Nil

**Conflict of interest:** None



**Fig. 1:** An example on PTX size measurement (done by taking the radial distance—in millimeters—between the parietal and the visceral pleura/mediastinum)

21 patients on positive pressure ventilation (PPV) in the observation arm, 8 patients failed. The authors concluded that TT was recommended in ventilated patients. Later, in 1999, Brasel et al.<sup>2</sup> conducted a RCT with eight patients in each arm (TT vs observation) and no difference in the progression of the PTX was observed, regardless of mechanical ventilation. A previous work by Cropano et al.<sup>10</sup> concluded that patients with PTXs  $\leq 35$  mm can be safely observed, even in ventilated patients. The 35-mm rule was created as an objective method to predict successful observation of PTX, regardless of mechanical ventilation. However, with a few trail in literature,<sup>2,8,9</sup> the management of PTXs in ventilated patients remains debatable.

The purpose of this study is to further explore the application of the 35-mm rule to observe PTXs in ventilated patients.

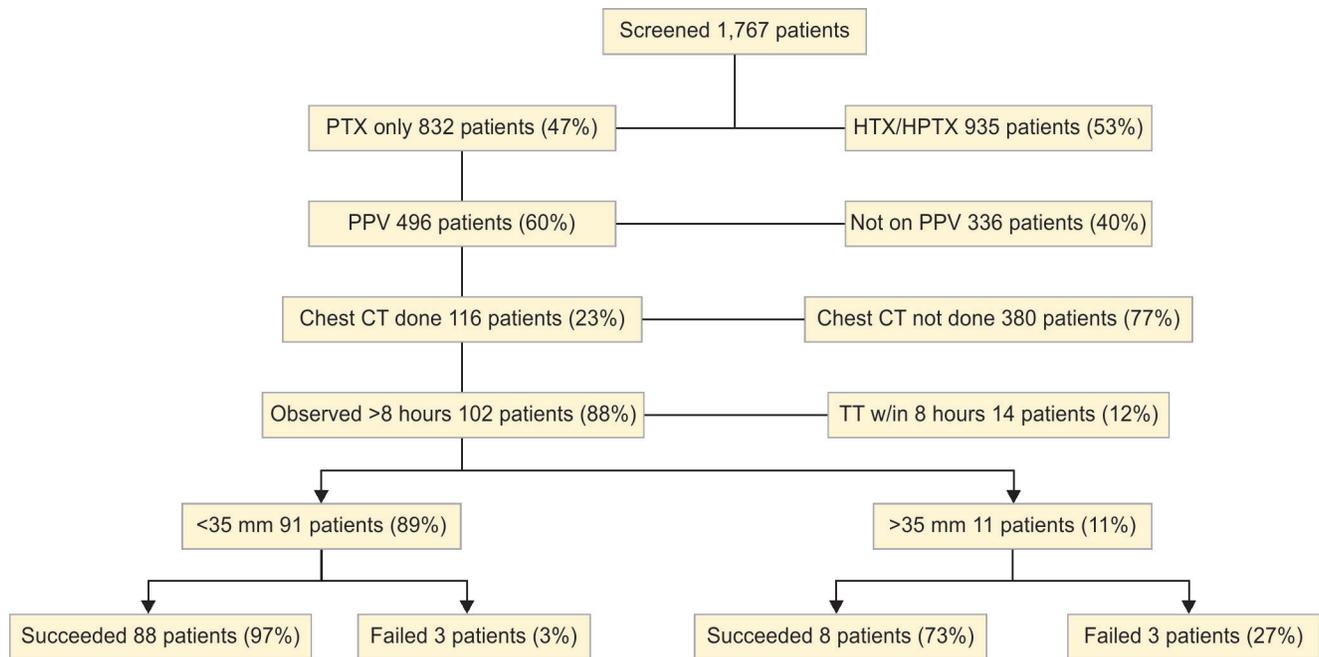
## METHODS OF RESEARCH

This was a single-center retrospective chart review of trauma patients admitted to a level 1 trauma center over 5 years (January 2011 to December 2016). The trauma registry at our institution was reviewed to identify the cohort. We included all patients on PPV, specifically endotracheal tube with mechanical ventilation, aged 18 years and above and who had a chest CT at the time of admission. We excluded patients who did not have a chest CT performed at the time of admission, had an ipsilateral hemothorax (HTX) or hemopneumothorax (HPTX), had a TT inserted prior to getting a chest CT, i.e., received a diagnosis of PTX based on Chest X-ray (CXR) without a subsequent CT, and patients without chest CT.

Chest CTs were reviewed for each patient to measure the size of the PTX, in millimeters (mm), by taking the radial distance—a line perpendicular to the chest wall—between the parietal and the visceral pleura/mediastinum on axial imaging. Measurements were then dichotomized into those measuring  $\leq 35$  mm and those measuring  $>35$  mm (Fig. 1).

The management of each case was categorized into those who were observed and those who underwent immediate TT. Observation was determined to be no intervention within 8 hours of presentation to the Emergency Department. The primary outcome was failure of observation of the PTX defined as a need for delayed TT or the need for secondary inventions including video-assisted thoracoscopic surgery (VATS), intrapleural tissue plasminogen activator, or thoracotomy. Delayed TT was either due to the expansion of the PTX detected on repeat imaging or physiologic deterioration, defined as two out of four of the following: respiratory rate greater than 30 breaths per minute, SpO<sub>2</sub> less than 94% on room air, heart rate greater than 100 beats per minutes, or systolic blood pressure less than 90 mm Hg attributed to the PTX.

We analyzed our data using IBM Corp. Released 2013 IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp. Mann-Whitney U test, t tests, or Chi-square tests were applied to evaluate



**Fig. 2:** Flowchart of included patients

**Table 1:** Demographics and trauma characteristics (N = 116)

Variable	All patients, N = 116	Successful observation, n = 96	Failed observation, n = 6	p value
	Frequency	Frequency	Frequency	
Age	(33.0, 22.0–53.0)	(32.0, 21.0–53.0)	(53.5, 29.0–66.3)	0.105
Race				0.216
White	71 (61.2%)	54 (56.3%)	6 (100.0%)	
Non-white	38 (32.7%)	35 (36.7%)	0	
Unknown	7 (6.0%)	7 (7.3%)	0	
Sex				0.161
Male	90 (77.6%)	72 (75.0%)	6 (100.0%)	
BMI	(27.3 ± 5.4)	(27.1 ± 5.7)	(26.3 ± 2.9)	0.778
Chronic obstructive pulmonary disease (COPD)				0.802
No	115 (99.1%)	95 (99.0%)	6 (100.0%)	
Yes	1 (0.9%)	1 (1.0%)	0	
ED systolic blood pressure (mean ± SD)	(132.5 ± 33.2)	(131.2 ± 33.0)	(133.5 ± 29.0)	0.867
ED diastolic blood pressure (mean ± SD)	(81.4 ± 21.3)	(81.3 ± 21.2)	(80.2 ± 17.5)	0.910
ED heart rate (mean ± SD)	(96.6 ± 27.0)	(96.1 ± 27.7)	(99.3 ± 21.9)	0.781
ED respiratory rate (mean ± SD)	(20.9 ± 7.1)	(21.0 ± 7.3)	(21.6 ± 9.4)	0.853
ED SpO2 (median, IQR)	(100.0, 95.8–100.0)	(96.8 ± 5.9)	(98.5, 98.0–100.0)	0.950
Mechanism of injury				0.721
Blunt	114 (98.3%)	94 (97.9%)	6 (100.0%)	
Penetrating	2 (1.7%)	2 (2.1%)	0	
GCS (median, IQR)	(3.0, 3.0–11.8)	(4.0, 3.0–12.8)	(8.5, 3.0–15.0)	0.544
13–15	28 (24.1%)	24 (25.0%)	3 (50.0%)	
9–12	9 (7.8%)	7 (7.3%)	0	
<9	79 (68.1%)	65 (67.7%)	3 (50.0%)	
ISS (mean ± SD)	(23.4 ± 8.8)	(23.3 ± 9.2)	(20.5, 18.5–23.8)	0.608
<9	2 (1.7%)	2 (2.1%)	0	
9–14	16 (13.8%)	14 (14.6%)	0	
15–24	52 (44.8%)	42 (43.8%)	5 (83.3%)	
≥25	46 (39.7%)	38 (39.6%)	1 (16.7%)	
ED disposition				
Operating room	24 (20.7%)	19 (19.8%)	2 (33.3%)	
ICU	90 (77.6%)	76 (79.2%)	3 (50.0%)	
Floor	2 (1.7%)	1 (1.0%)	1 (16.7%)	
ICU days (median, IQR)	(4.0, 2.0–10.0)	(4.0, 2.0–10.8)	(5.0, 1.0–13.3)	0.989
LOS days (median, IQR)	(10.5, 4.0–21.8)	(10.0, 4.0–20.8)		0.322
In-hospital mortality	29 (25.0%)	25	0	0.150

the association of continuous or categorical variables, with failure of observation as an outcome. The study was approved by the Intuition Review Board (IRB) at the Medical College of Wisconsin (MCW).

## RESULTS

A total of 1,767 patients with PTX were identified from our trauma registry. Nine hundred thirty-five (53%) patients were excluded for having an ipsilateral HTX or HPTX. Of the remaining 832 patients, 496 (60%) required PPV and 116 (23%) had a chest CT done at the time of admission (Fig. 2).

Table 1 shows the demographics and trauma characteristics of our cohort. The median age was 33.0 years (IQR, 22.0–53.0), 98.3% with a blunt chest injury. About 68.1% of patients had a Glasgow

Coma Scale (GCS) <9, and 44.8% had an injury severity score (ISS) of 15 to 24. The median length of stay (LOS) was 10.5 days (IQR, 4.0–21.8), and the intensive care unit (ICU) LOS was 4.0 days (IQR, 2.0–10.0).

Table 2 shows the characteristics of the chest injury. Of the 116 patients, 50.9% of patients had ≥3 rib fractures, only 0.9% had a clinical flail chest diagnosis, and 56.0% had a lung contusion. A total of 14 (12%) patients received immediate TT (within 8 hours of presentation). The remaining 102 patients (88%) were observed for more than 8 hours; 96 (94%) of those were successfully observed, while 6 patients (6%) failed observation (Table 3 and Fig. 2). The median measurement of the PTX in patients with successful observation (94.0%) was 9.2 mm (IQR, 4.3–18.5) with 91.7% measuring ≤35 mm. The median measurement for patients failing observation (6.0%) was 32.9 mm (IQR, 9.5–73.1) with 50.0% measuring >35 mm.

**Table 2:** Description of the chest injuries and pneumothoraces (N = 102)

Variable	Observed (N = 102)		p value
	Successful (n = 96) Frequency	Failed (n = 6) Frequency	
<b>Chest injury</b>			
No. of fractured ribs			0.586
0	33 (34.4%)	2 (33.3%)	
1–2	16 (16.7%)	0	
≥3	47 (49.0%)	4 (66.7%)	
<b>Flail chest</b>			
No	96 (100.0%)	6 (100.0%)	
Yes	0	0	
<b>Lung contusion</b>			
No	42 (43.2%)	3 (50.0%)	0.765
Yes	54 (56.3%)	3 (50.0%)	
<b>Pneumothorax measurement (median, IQR)</b>			
≤35 mm	(9.2, 4.3–18.5) 88 (91.7%)	(32.9, 9.5–73.1) 3 (50.0%)	<b>0.015</b>
>35 mm	8 (8.3%)	3 (50.0%)	

**Table 3:** Management and hospital course (N = 102)

Variable	Observed (N = 102)		p value
	Successful (n = 96) Frequency	Failed (n = 6) Frequency	
<b>TT</b>			
No	96 (100%)	0	
Yes	0	6 (100%)	
<b>Chest tube placement (hour after trauma) (median, IQR)</b>			
		(24.5, 16.5–180.0)	
<b>Management</b>			
Initially observed (at most 8 hour)	96 (100%)	6 (100%)	
Failed observation	0	6 (100%)	
<b>Reason for failing observation</b>			
<b>Progression on imaging</b>			
<b>Hemodynamic instability</b>			
<b>Ventilation days (median, IQR)</b>			
1–5	(2.5, 1.0–8.0) 67 (69.8%)	(4.0, 1.0–5.5) 5 (83.3%)	0.959
6–10	9 (9.4%)	1 (16.7%)	
>10	20 (20.8%)	0	
<b>Ventilation settings</b>			
Lower end of MAP range (median, IQR)	(7.9, 7.0–8.9)	(7.2, 6.6–9.4)	0.545
Higher end of MAP range (median, IQR)	(11.0, 9.4–14.0)	(12.0, 10.5–14.0)	0.748
Highest positive end-expiratory pressure (PEEP) (median, IQR)	(5.0, 5.0–7.4)	(5.0, 5.0–5.8)	0.515
Lower end of tidal volume range (mean ± SD)	(542.9 ± 79.3)	(541.7 ± 37.6)	0.969
Higher end of tidal volume range (mean ± SD)	(571.4 ± 84.1)	(591.7 ± 37.6)	0.560

In 66.7% of cases, the reason for failing observation was due to the progression of the PTX on imaging (CT scan or chest X-ray) due to hemodynamic instability in 33.3% of the patients. The majority (71.6%) of patients were put on PPV with a median ventilation duration of 2.5 days (IQR, 1.0–7.0). The median of the lower end of the mean airway pressure (MAP) range was 7.8 mm Hg (IQR, 6.9–9.0) and of the higher end of the MAP range was 12.0 mm Hg (IQR, 9.4–15.0). The median of the highest positive end-expiratory pressure (PEEP) was 5.0 mm Hg (IQR, 5.0–7.9). The mean of the lower end of the tidal volume range was 546.9 ± 80.3 mL and of the higher end of the tidal volume range

was 576.9 ± 83.9 mL. There was no statistically significant difference in failure rates based on any of the ventilation settings (Table 3).

On the univariate analysis, PTX measurement both as a continuous and categorical value ( $p = 0.015$ ) was significant for predicting failure of observation (Tables 1 to 3). The negative predictive value for 35 mm as a cutoff was 96.7% to predict successful observation.

## DISCUSSION

Observing hemodynamically stable patients with PTX continues to be a debatable topic. This is particularly concerning when a

patient requires PPV. The increased pressures are thought to cause an expansion of the PTX and subsequent physiologic deterioration. This intuitively prompts physicians to place prophylactic TTs even when the PTX size is minimal. There is a need to minimize the use of unnecessary TTs and spare patients the associated comorbidities.

Cumulative work by de Moya et al.<sup>11</sup> thus far created the 35 mm rule, and here we have advanced these data by showing that the 35-mm rule is also safe in hemodynamically stable patients on PPV. The study conducted by Cropano et al. included 165 patients, of whom 21 were on PPV and all were successfully observed. In our study, we were able to verify that the 35 mm rule is safe in a larger cohort of isolated PPV patients at a different institution. Thus, we overcome one of the limitations of the previous study. Applying the 35 mm rule, patients with PTX  $\leq$ 35 mm may be successfully observed, with a success rate of 97%.

Some of the limitations of our study are rooted in its retrospective nature. The decision to place a TT is based on the available medical record documentation and the reasoning of the physician often remains unclear. There is a need for a prospective and randomized study to validate these results. This study also lacks long-term follow-up, as patients were only followed until discharge. Lastly, the PTX measurements were not performed by a radiologist, though the measurements were internally validated by the researchers.

In conclusion, the 35 mm rule remains an objective, clinician-friendly, rapid tool to guide the management of the hemodynamically stable ventilated patient, in an effort to spare patients unnecessary TTs. Patients on PPV with PTX measuring  $\leq$ 35 mm on chest CT can be safely observed at institutions with appropriate monitoring capacity.

### CLINICAL SIGNIFICANCE

This rule might serve as an objective clinician-friendly rapid tool to guide the management of hemodynamically ventilated patients with PTX.

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## COMMENTARY

The management of the trauma patient continuously creates new challenges for the trauma team. One of the fundamental tenets in medicine and surgery is to do no harm. Under this mind frame, trauma surgeons in the active clinical field are always in search of performing the least amount of possible invasive procedures for the benefit of the patient. In contrast, advances in technology and imaging have exponentially increased the resolution of radiological studies. Incidental findings displayed on CT scans performed as part of the initial trauma workup particularly create specific decision-making dilemmas in management.

A perfect example is the finding of an occult PTX in a CT scan, not visualized in the initial chest X-ray. How should we manage this injury? Should we place a chest tube on all of them? Is it really necessary? What percentage will progress to be of clinical significance? A major challenge occurs when the patients are or will be exposed to PPV. I applaud the authors for presenting their data on a topic in which, honestly, every trauma surgeon has their own opinion and belief based on their past experiences. Their attempt to standardize this management supported by evidence-based medicine is commendable. I agree with the authors that there is a high percentage of chest tube placements in small-sized pneumothoraces which most likely did not require placement of the tube at all and could have been avoided with appropriate monitoring. In theory, this practice could prevent the comorbidities associated with this procedure.

Drainage complications, in one study, occurred in 15% of those randomized to drainage, while suboptimal TT position occurred in an additional 15%. There were three times (24 vs 8%) more failures and more respiratory distress ( $p = 0.01$ ) among those observed with occult pneumothoraces requiring sustained PPV vs just for an operation, which increases threefold after a week in the intensive care unit ( $p = 0.07$ ). Their results suggest that occult pneumothoraces may be safely observed in hemodynamically stable patients undergoing PPV just for an operation, although one-third of those requiring a week or more of intensive care received drainage, and tension pneumothoraces still occurred. Complications of pleural drainage remain unacceptably high, and future work should attempt to delineate specific factors among those observed that warrant prophylactic drainage.<sup>1</sup> Also, the limited use of chest tubes could decrease the rate of development of pneumonias in patients with rib fractures with an underlying pulmonary contusion.<sup>2</sup>

One of the largest studies evaluating the management of occult pneumothoraces demonstrated that almost half (46%) of them were treated conservatively. Two hundred fifty-two of 277 patients in this cohort (90%) did not require subsequent chest tube insertion, including the majority of patients (56 of 62 [90%]) who were receiving PPV on admission. The hazard ratio (HR) for failure of conservative management showed no difference between the ventilated and nonventilated patients (HR, 1.1;  $p = 0.84$ ). Only the presence of a large HTX was associated with an increased likelihood of failure of conservative management.<sup>3</sup> However, the authors did not provide an initial specific criterion (the size of the PTX) to guide the surgeon's decision in placing a chest tube.

Again, I encourage the authors to expand their retrospective review and/or develop a distinctive prospective study detailing their management of these occult pneumothoraces in a well-controlled randomized double-blinded study. Developing

guidelines that include clinical data of the patient will support their recommendations for this specific management. I would like to recommend that further studies are also necessary to confirm the adequate size of occult pneumothoraces requiring a chest tube placement for patients who do not require PPV during their hospitalization.

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## COMMENTARIO

El manejo del paciente con múltiples lesiones severas crea continuamente nuevos desafíos para el equipo de trauma. Uno de los principios fundamentales de la medicina y la cirugía es no hacer daño. Bajo este marco mental, los cirujanos de trauma en el campo clínico están siempre buscando la mejor manera de evitar procedimientos invasivos innecesarios para el beneficio del paciente. En contraste, los avances en tecnología y desarrollo de imágenes han aumentado exponencialmente la resolución de los estudios radiológicos. Los hallazgos incidentales encontrados en las tomografías computarizadas (TC) realizadas como parte de la evaluación inicial del paciente crean dilemas particularmente en la toma de decisiones clínicas.

Un ejemplo es el hallazgo de un neumotórax oculto en la tomografía computarizada, que no se visualiza en la radiografía de tórax inicial. ¿Cómo debemos manejar esta lesión? ¿Deberíamos colocar un tubo torácico en todos ellos? ¿Es realmente necesario? ¿Qué porcentaje progresará para ser de importancia clínica? Un gran desafío ocurre cuando los pacientes están o estarán expuestos a ventilación con presión positiva. Aplaudo a los autores por presentar sus datos sobre un tema en el que, honestamente, cada cirujano especialista en trauma tiene su propia opinión y creencia basada en la experiencia. Su intento de estandarizar este manejo apoyado por la medicina basada en la evidencia es encomiable. Estoy de acuerdo con los autores en que hay un alto porcentaje de colocaciones de tubos torácicos por neumotóraces de pequeño tamaño que probablemente no lo necesitaban y podrían haberse evitado con un monitoreo apropiado. En teoría, esta práctica podría prevenir las comorbilidades asociadas con este procedimiento.

Complicaciones con el drenaje, en un estudio, ocurrieron en el 15% de las personas asignadas al azar a este procedimiento, mientras que la posición subóptima del tubo ocurrió en un 15% de casos adicionales. Hubo un porcentaje tres veces mayor (24% frente a 8%) de falla y dificultad respiratoria ( $p = 0.01$ ) entre los

observados con neumotoraces ocultos que requirieron ventilación con presión positiva sostenida en comparación con los pacientes que solamente requirieron una sola operación; este porcentaje se triplica al paciente encontrarse más de una semana en la unidad de cuidados intensivos ( $p = 0.07$ ). Sus resultados sugieren que los neumotoraces ocultos pueden observarse de manera segura en pacientes hemodinámicamente estables sometidos a ventilación con presión positiva relacionado solamente a una operación, aunque un tercio de los que requieren una semana o más de cuidados intensivos recibieron un tipo de drenaje de todos modos, y aún se produjeron neumotoraces a tensión. Las complicaciones del drenaje pleural siguen siendo inaceptablemente altas, y trabajos en el futuro deben tratar de delinear los factores específicos que justifiquen el drenaje profiláctico.<sup>1</sup> Además, el uso limitado de tubos torácicos podría disminuir la tasa de desarrollo de neumonías en pacientes con fracturas de costillas con una contusión pulmonar subyacente.<sup>2</sup>

Uno de los estudios más abarcadores que evaluaron el manejo de neumotoraces ocultos demostró que casi la mitad (46%) de ellos fueron tratados de forma conservadora. Doscientos cincuenta y dos de los 277 pacientes en este grupo (90%) no requirieron una inserción subsecuente del tubo torácico, aún incluyendo la mayoría de los pacientes (56 de 62 [90%]) que recibieron ventilación

con presión positiva al ingreso. La razón de riesgo (HR) para el fracaso del tratamiento conservador no mostró diferencias entre los pacientes ventilados y no ventilados (HR, 1.1;  $p = 0.84$ ). Solo la presencia de un hemotórax de gran tamaño se asoció con una mayor probabilidad de fracaso del manejo conservador.<sup>3</sup> Sin embargo, los autores no proporcionaron un criterio específico inicial (tamaño del neumotórax) para guiar la decisión del cirujano al colocar un tubo torácico.

Una vez más, aliento a los autores a ampliar su revisión retrospectiva y/o desarrollar un estudio prospectivo distintivo que detalle su manejo de estos neumotoraces ocultos en un estudio aleatorizado y controlado. El desarrollo de pautas que incluyan datos clínicos del paciente respaldará sus recomendaciones para este manejo en específico. Además, me gustaría recomendar que también se necesitan estudios en general para confirmar el tamaño adecuado de los neumotoraces ocultos que requieren una colocación de un tubo torácico para pacientes que no serán expuestos a la ventilación con presión positiva durante su hospitalización.

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