

Señores
Superintendencia de Industria y Comercio
Dirección de Nuevas Creaciones
L. C

Ref.: Respuesta a requerimiento de fondo

Expediente: NC2019/0007275

Solicitante: Universidad de Manizales

Título: ***“SIMULADOR DE MEDIANA-ALTA FIDELIDAD PARA ENTRENAMIENTO DE TORACOSTOMIA CERRADA Y SU METODO”***

ADRIANA RAVE VALENCIA, actuando en nombre y representación de UNIVERSIDAD DE MANIZALES, me permito dar respuesta dentro del plazo legal al requerimiento de examen de fondo de la patente de la referencia, como se presenta a continuación.

Respecto a las observaciones sobre la solicitud de patente:

1. Afirma el examinador: *“la unidad de medida “Fr” en la reivindicación 1 no corresponde a las unidades establecidas por el Sistema Internacional de Medidas, por lo tanto, se solicita hacer las modificaciones respectivas”.*

Sobre este punto, es preciso señalar lo siguiente:

Esta unidad de medida, se encuentra en dos apartados del manuscrito de la patente:

- **VIII. DESCRIPCIÓN DETALLADA DE LA INVENCION:** *El Tubo de toracostomía (2) consiste en un tubo plástico para la realización de toracostomía que se puede encontrar entre los calibres 8 y 40 Fr.*
- **XI. REIVINDICACIONES:** *Un tubo de toracostomía (2) que consiste en un tubo plástico entre los calibres 8 y 40 Fr.*

French (Fr) es una unidad de medida que hace referencia al diámetro externo de tubos cilíndricos. *Se usa en múltiples dispositivos médicos como sondas y catéteres. Se encuentra en uso desde el siglo XIX y se conoce como la escala francesa o la escala de Charrière en honor a su inventor.* Un Fr equivale a 0,333 milímetros (mm). Es decir, un tubo de toracostomía de 8 Fr tiene un diámetro externo de 2,66 mm y uno de 40 Fr tiene un diámetro externo de 13,32 mm (**Tomado de:** Cooke, D.T., David, E.A., 2013. Large-Bore and Small-Bore Chest Tubes: Types, Function, and Placement. Thorac. Surg. Clin. 23, 17–24. <https://doi.org/10.1016/j.thorsurg.2012.10.006>)

Adjunto se presenta el artículo citado para ampliación del tema.

Ahora bien, con relación a la invención, se realiza entonces una conversión de la medida Fr a milímetros (mm), quedando las expresiones objetadas, así:

VIII. DESCRIPCIÓN DETALLADA DE LA INVENCIÓN: *El Tubo de toracostomía (2) consiste en un tubo plástico para la realización de toracostomía que se puede encontrar entre 2,66 milímetros y 13,32 milímetros de diámetro externo (Calibres 8 a 40 French. Un French equivale a 0,333 milímetros).*

XI. REIVINDICACIONES: *Un tubo de toracostomía (2) que consiste en un tubo plástico entre 2,66 mm y 13,32 mm de diámetro externo.*

2. En el punto 2 de las observaciones a las reivindicaciones, el examinador indica que *“la redacción de las reivindicaciones 2 a 6 no es clara, dado que, si son reivindicaciones dependientes de la reivindicación independiente 1, estas deben ser escritas de la siguiente forma: “El simulador de mediana-alta fidelidad para -entrenamiento de toracostomía cerrada de la reivindicación 1, caracterizado porque el maniquí de simulación (...)”.* Se solicita realizar las correcciones respectivas.

Para subsanar este punto, se procede a realizar ajustes en el encabezado de cada una de las reivindicaciones, quedando como se presenta en el nuevo capítulo de reivindicaciones descrito en el último punto de la respuesta.

3. Con relación a la objeción: *“la reivindicación 6 hace referencia a “Intel i7 9700K”, “Nvidia RTX 2080”, “Windows”, y “Linux” que son marcas registradas que no definen el producto, porque sus características técnicas pueden cambiar con el paso del tiempo, aunque conserve el mismo nombre”,* se procede a eliminar estas referencias del capítulo reivindicatorio.
4. Finalmente, el examinador solicita modificar la reivindicación 7 para darle forma de método, lo cual se corrigió.

A continuación se presenta el nuevo capítulo reivindicatorio:

REIVINDICACIONES

1. Simulador de mediana-alta fidelidad para entrenamiento de toracostomía cerrada, caracterizado porque comprende:
 - a. Un maniquí de simulación de toracostomía cerrada (1) que consiste en una caja torácica (1a) a escala 1:1 de una persona adulta. En su interior, la caja torácica (1a) cuenta con órganos sintéticos (1b). En el exterior, la caja torácica (1a) cuenta con un revestimiento en capas.
 - b. Un tubo de toracostomía (2) que consiste en un tubo plástico entre 2,66 mm y 13,32 mm de diámetro externo. En la región distal del tubo o en sus regiones laterales, o en ambas, se encuentra un sensor electrónico (2a)

de determinación de movimientos en tiempo real y de registro de parámetros de desempeño durante la realización del procedimiento. Estos parámetros incluyen la trayectoria del tubo y su ubicación final, el número de errores cometidos durante el procedimiento y su descripción, el tiempo requerido para completar la tarea satisfactoriamente y la evaluación de la mejora de estos parámetros a través de la repetición del entrenamiento.

- c. Un equipo para seguimiento de la trayectoria (3) del tubo de toracostomía (2) que consiste en una cámara de video (3a) que puede ubicarse arriba, o a los lados, o ambos, de la caja torácica (1a) del maniquí de simulación de toracostomía cerrada (1); un emisor-receptor de datos inalámbrico o conectado por cables (3b), basado en un sistema embebido; y un instrumento de calibración (3c), consistente en una mesa o plataforma blanca que tiene demarcados con color negro trazos cuadriculados de entre 0.5-10 cm x 0.5-10 cm cada uno, y sobre la cual se encuentra el maniquí de simulación de toracostomía cerrada (1). El equipo para seguimiento de la trayectoria (3) del tubo de toracostomía (2) transmite la información obtenida a un sistema computacional (5), al cual se encuentra acoplado.
 - d. Un sistema computacional (5) del tipo ordenador de escritorio, que contiene como mínimo una central de procesamiento, una memoria de almacenamiento interno, una tarjeta de red, una tarjeta de video, un sistema operativo, una interfaz de usuario, programas de procesamiento de texto, hojas de cálculo, dispositivos de entrada tipo teclado y *mouse* y dispositivos de salida tipo sistema de audio y pantallas LCD.
 - e. Instrumental quirúrgico (6) que se utiliza para este procedimiento y que consiste en dos campos estériles (6a), una hoja de bisturí número 11 o 15 (6b), un mango de bisturí número 3 (6c) en acero quirúrgico, dos pinzas tipo Kelly (6d) en acero quirúrgico, unas tijeras rectas (6e) en acero quirúrgico y una unidad de hilo de sutura quirúrgica estéril no absorbible (6f).
 - f. Un sistema recolector (7) que consiste en un equipo de drenaje que puede ser pasivo (válvula de Heimlich o con sello de agua) o activo (sistema de tres frascos o digital).
- 2. El simulador de mediana-alta fidelidad para entrenamiento de toracostomía cerrada de la reivindicación 1, caracterizado porque el maniquí de simulación (1) puede comprender, además, estructuras antropomorfas de cabeza y cuello, y de miembros superiores e inferiores.
 - 3. El simulador de mediana-alta fidelidad para entrenamiento de toracostomía cerrada de la reivindicación 1, caracterizado porque el maniquí de simulación (1) puede comprender, además, pulmones de silicona o látex (1e) que pueden ser conectados, a través de una interfaz invasiva como un tubo endotraqueal (1f) o

de traqueostomía (1g), a un sistema bomba-válvula-mascarilla (1h) o a un ventilador mecánico convencional de presión negativa (1i).

4. El simulador de mediana-alta fidelidad para entrenamiento de toracostomía cerrada de la reivindicación 1, caracterizado porque el maniquí de simulación (1) puede comprender, además, sensores de proximidad (1c) adheridos a los órganos sintéticos (1b).
5. El simulador de mediana-alta fidelidad para entrenamiento de toracostomía cerrada de la reivindicación 1, caracterizado porque la caja torácica (1a) contenida en el maniquí de simulación (1) puede comprender, además, al menos una carga de material de aspiración ubicado en la región apical o posterior e inferior de la cavidad pleural derecha o izquierda, contenida en un reservorio de fácil ruptura (1d).
6. El simulador de mediana-alta fidelidad para entrenamiento de toracostomía cerrada de la reivindicación 1, caracterizado porque el sistema computacional (5) posee las siguientes prestaciones mínimas:
 - - Una central de procesamiento con puertos USB, HDMI y VGA.
 - - Una memoria RAM de dieciséis gigas.
 - - Capacidad de almacenamiento interno de 2 TB HDD o SSD
 - - Una tarjeta de red de 10/100/1000 Mbps
 - - Una tarjeta gráfica
 - - Un sistema operativo
 - - Dos pantallas LCD de entre 30 y 40 pulgadas
7. Un método (8) para la ejecución de un simulador de mediana-alta fidelidad para entrenamiento de toracostomía cerrada, caracterizado porque a través de un instrumento con conjunto de instrucciones para la evaluación de desempeño (4), gestiona los datos recopilados de una forma ordenada secuencialmente en el tiempo, en un proceso que comprende las siguientes etapas:
 - a. Crear un registro de instructor o alumno nuevo, o recuperar información para instructor o alumno registrado.
 - b. Calibrar el sensor electrónico (2a) del tubo de toracostomía (2), y del equipo para seguimiento de la trayectoria (3) del tubo de toracostomía (2).
 - c. Introducir información del caso clínico estandarizado que se va a simular con patrones correctos e incorrectos de ejecución de una toracostomía cerrada.
 - d. Visualizar constantes vitales del paciente, objeto del caso clínico estandarizado, antes, durante y después de finalizado el procedimiento.
 - e. Capturar la información recopilada por los sensores de proximidad (1c) que se encuentran en los órganos sintéticos (1b) que están en el interior de la caja torácica (1a) del maniquí de simulación de toracostomía cerrada (1), y/o por el sensor electrónico (2a) del tubo de toracostomía (2), relacionada con la correcta o incorrecta trayectoria del tubo y su ubicación final, su proximidad con órganos internos, el número de errores

- cometidos durante el procedimiento y su descripción, el tiempo requerido para completar la tarea satisfactoriamente y la determinación de la mejora de estos parámetros a través de la repetición del entrenamiento.
- f. Notificar visual y/o auditivamente el desempeño en tiempo real, tanto para el instructor como para el alumno, durante la realización del procedimiento.
 - g. Generar imagen 2D de características radiográficas, donde se evidencia la ubicación final del tubo, según el desempeño del alumno.
 - h. Almacenar localmente y enviar a servidor remoto, la información recopilada durante cada entrenamiento.
 - i. Visualizar un reporte final de desempeño con respecto a cómo se desarrolló técnicamente cada individuo durante su entrenamiento en la realización de una toracostomía cerrada.
8. El simulador de mediana-alta fidelidad para entrenamiento de toracostomía cerrada de la reivindicación 1, caracterizado porque la caja torácica (1a) del maniquí de simulación (1) y los órganos sintéticos (1b) pueden ser construidos con filamentos de PLA, ABS, TPU o Nylon o la combinación de estos materiales.
9. El simulador de mediana-alta fidelidad para entrenamiento de toracostomía cerrada de la reivindicación 1, caracterizado porque el revestimiento en capas de la caja torácica (1a) del maniquí de simulación (1) consiste, desde afuera hacia adentro, en una cubierta de silicona, látex, plástico o TPU o la combinación de estos materiales.

Finalmente, considerando que se realizaron modificaciones a la solicitud de patente, se realizó el pago de la tasa oficial correspondiente de manera que sean tenidas en cuenta por la oficina de patentes a efectos de superar las objeciones planteadas.

Del señor director de nuevas creaciones,



Adriana Rave
Apoderada

NUEVO CAPITULO REIVINDICATORIO

1. Simulador de mediana-alta fidelidad para entrenamiento de toracostomía cerrada, caracterizado porque comprende:
 - a. Un maniquí de simulación de toracostomía cerrada (1) que consiste en una caja torácica (1a) a escala 1:1 de una persona adulta. En su interior, la caja torácica (1a) cuenta con órganos sintéticos (1b). En el exterior, la caja torácica (1a) cuenta con un revestimiento en capas.
 - b. Un tubo de toracostomía (2) que consiste en un tubo plástico entre 2,66 mm y 13,32 mm de diámetro externo. En la región distal del tubo o en sus regiones laterales, o en ambas, se encuentra un sensor electrónico (2a) de determinación de movimientos en tiempo real y de registro de parámetros de desempeño durante la realización del procedimiento. Estos parámetros incluyen la trayectoria del tubo y su ubicación final, el número de errores cometidos durante el procedimiento y su descripción, el tiempo requerido para completar la tarea satisfactoriamente y la evaluación de la mejora de estos parámetros a través de la repetición del entrenamiento.
 - c. Un equipo para seguimiento de la trayectoria (3) del tubo de toracostomía (2) que consiste en una cámara de video (3a) que puede ubicarse arriba, o a los lados, o ambos, de la caja torácica (1a) del maniquí de simulación de toracostomía cerrada (1); un emisor-receptor de datos inalámbrico o conectado por cables (3b), basado en un sistema embebido; y un instrumento de calibración (3c), consistente en una mesa o plataforma blanca que tiene demarcados con color negro trazos cuadriculados de entre 0.5-10 cm x 0.5-10 cm cada uno, y sobre la cual se encuentra el maniquí de simulación de toracostomía cerrada (1). El equipo para seguimiento de la trayectoria (3) del tubo de toracostomía (2) transmite la información obtenida a un sistema computacional (5), al cual se encuentra acoplado.
 - d. Un sistema computacional (5) del tipo ordenador de escritorio, que contiene como mínimo una central de procesamiento, una memoria de almacenamiento interno, una tarjeta de red, una tarjeta de video, un sistema operativo, una interfaz de usuario, programas de procesamiento de texto, hojas de cálculo, dispositivos de entrada tipo teclado y *mouse* y dispositivos de salida tipo sistema de audio y pantallas LCD.
 - e. Instrumental quirúrgico (6) que se utiliza para este procedimiento y que consiste en dos campos estériles (6a), una hoja de bisturí número 11 o 15 (6b), un mango de bisturí número 3 (6c) en acero quirúrgico, dos pinzas tipo Kelly (6d) en acero quirúrgico, unas tijeras rectas (6e) en acero quirúrgico y una unidad de hilo de sutura quirúrgica estéril no absorbible (6f).

- f. Un sistema recolector (7) que consiste en un equipo de drenaje que puede ser pasivo (válvula de Heimlich o con sello de agua) o activo (sistema de tres frascos o digital).
2. El simulador de mediana-alta fidelidad para entrenamiento de toracostomía cerrada de la reivindicación 1, caracterizado porque el maniquí de simulación (1) puede comprender, además, estructuras antropomorfas de cabeza y cuello, y de miembros superiores e inferiores.
3. El simulador de mediana-alta fidelidad para entrenamiento de toracostomía cerrada de la reivindicación 1, caracterizado porque el maniquí de simulación (1) puede comprender, además, pulmones de silicona o látex (1e) que pueden ser conectados, a través de una interfaz invasiva como un tubo endotraqueal (1f) o de traqueostomía (1g), a un sistema bomba-válvula-mascarilla (1h) o a un ventilador mecánico convencional de presión negativa (1i).
4. El simulador de mediana-alta fidelidad para entrenamiento de toracostomía cerrada de la reivindicación 1, caracterizado porque el maniquí de simulación (1) puede comprender, además, sensores de proximidad (1c) adheridos a los órganos sintéticos (1b).
5. El simulador de mediana-alta fidelidad para entrenamiento de toracostomía cerrada de la reivindicación 1, caracterizado porque la caja torácica (1a) contenida en el maniquí de simulación (1) puede comprender, además, al menos una carga de material de aspiración ubicado en la región apical o posterior e inferior de la cavidad pleural derecha o izquierda, contenida en un reservorio de fácil ruptura (1d).
6. El simulador de mediana-alta fidelidad para entrenamiento de toracostomía cerrada de la reivindicación 1, caracterizado porque el sistema computacional (5) posee las siguientes prestaciones mínimas:
 - - Una central de procesamiento con puertos USB, HDMI y VGA.
 - - Una memoria RAM de dieciséis gigas.
 - - Capacidad de almacenamiento interno de 2 TB HDD o SSD
 - - Una tarjeta de red de 10/100/1000 Mbps
 - - Una tarjeta gráfica
 - - Un sistema operativo
 - - Dos pantallas LCD de entre 30 y 40 pulgadas
7. Un método (8) para la ejecución de un simulador de mediana-alta fidelidad para entrenamiento de toracostomía cerrada, caracterizado porque a través de un instrumento con conjunto de instrucciones para la evaluación de desempeño (4), gestiona los datos recopilados de una forma ordenada secuencialmente en el tiempo, en un proceso que comprende las siguientes etapas:
 - a. Crear un registro de instructor o alumno nuevo, o recuperar información para instructor o alumno registrado.

- b. Calibrar el sensor electrónico (2a) del tubo de toracostomía (2), y del equipo para seguimiento de la trayectoria (3) del tubo de toracostomía (2).
 - c. Introducir información del caso clínico estandarizado que se va a simular con patrones correctos e incorrectos de ejecución de una toracostomía cerrada.
 - d. Visualizar constantes vitales del paciente, objeto del caso clínico estandarizado, antes, durante y después de finalizado el procedimiento.
 - e. Capturar la información recopilada por los sensores de proximidad (1c) que se encuentran en los órganos sintéticos (1b) que están en el interior de la caja torácica (1a) del maniquí de simulación de toracostomía cerrada (1), y/o por el sensor electrónico (2a) del tubo de toracostomía (2), relacionada con la correcta o incorrecta trayectoria del tubo y su ubicación final, su proximidad con órganos internos, el número de errores cometidos durante el procedimiento y su descripción, el tiempo requerido para completar la tarea satisfactoriamente y la determinación de la mejora de estos parámetros a través de la repetición del entrenamiento.
 - f. Notificar visual y/o auditivamente el desempeño en tiempo real, tanto para el instructor como para el alumno, durante la realización del procedimiento.
 - g. Generar imagen 2D de características radiográficas, donde se evidencia la ubicación final del tubo, según el desempeño del alumno.
 - h. Almacenar localmente y enviar a servidor remoto, la información recopilada durante cada entrenamiento.
 - i. Visualizar un reporte final de desempeño con respecto a cómo se desarrolló técnicamente cada individuo durante su entrenamiento en la realización de una toracostomía cerrada.
8. El simulador de mediana-alta fidelidad para entrenamiento de toracostomía cerrada de la reivindicación 1, caracterizado porque la caja torácica (1a) del maniquí de simulación (1) y los órganos sintéticos (1b) pueden ser construidos con filamentos de PLA, ABS, TPU o Nylon o la combinación de estos materiales.
9. El simulador de mediana-alta fidelidad para entrenamiento de toracostomía cerrada de la reivindicación 1, caracterizado porque el revestimiento en capas de la caja torácica (1a) del maniquí de simulación (1) consiste, desde afuera hacia adentro, en una cubierta de silicona, látex, plástico o TPU o la combinación de estos materiales.

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Large-Bore and Small-Bore Chest Tubes

Types, Function, and Placement

David T. Cooke, MD*, Elizabeth A. David, MD

KEYWORDS

• Chest tubes • Small bore • Large bore • Effusions • French

KEY POINTS

- Large-bore chest tubes (LBCTs) are defined as 20 French (Fr) or greater and small-bore chest tubes (SBCTs) are less than 20 Fr.
- Fr is a unit of measurement referring to the outer diameter of the cylindrical tube. A Fr is equivalent to 0.333 mm.
- Chest tubes abide by the physics of Poiseuille's law (for fluids) and the Fanning equation (for air). An increase in the diameter of the tube leads to greater flow of fluid and air.
- With the exception of hemothorax and complex empyema, SBCTs should be considered as first-line pleural drainage therapy. If ineffective, then change to an LBCT or thorascopic surgical therapy should be the next intervention.
- SBCTs are likely ineffective for complex empyema and hemothorax, and LBCTs should be considered standard first-line therapy in that setting.

INTRODUCTION

Pleural tubes or chest tubes are drains that are placed in the pleural space, either surgically or percutaneously, to evacuate abnormal fluid or air. Indications for chest tubes include prophylaxis drainage of air, blood and other fluids after chest surgery (eg, pulmonary resection, esophageal surgery, pleural decortication, and so forth), and therapeutic drainage of pathologic pleural contents such as those found with pneumothorax, hemothorax, empyema, chylothorax, and malignant effusion. This article describes the differences between large-bore chest tubes (LBCTs) and small-bore chest tubes (SBCTs) and characterize the types of chest tubes. The advantages and disadvantages of using each size category, the comparative effectiveness of both tube subsets,

and basic techniques and clinical pearls for their placement are also discussed.

LBCT

Definition

Chest tubes can be divided into size categories of large bore (≥ 20 French) and small bore (< 20 French). French (Fr) is a unit of measurement first proposed by the French surgical instrument maker Joseph-Frederic-Benoit Charrière in the 1800s. Fr refers to the outer diameter of the cylindrical tube. A Fr is equivalent 0.333 mm. Therefore a 24-Fr chest tube has an outer diameter of 8 mm. Although the outer diameter of a chest tube is consistent, the inner diameter can be variable depending on the thickness of the wall of the chest tube, which varies according to the manufacturer.

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Two major types of LBCTs are the Argyle type (Covidien, Mansfield, MA) and the Axiom type (Axiom Medical Inc, Torrance, CA). Argyle tubes are made of either polyvinyl chloride (PVC) or silicone; the Axiom tubes are made of silicone. Both tubes contain 5 to 6 drainage holes or eyes extending from the tip (**Fig. 1**). Along the side of each chest tube is a radiopaque line that allows for identification of the chest tube on a plain chest radiograph. The last or most proximal eye is engineered through the radiopaque line so that it can be clearly seen the final hole is in the pleural space (**Fig. 2**). If the clinician chooses to add more holes to the chest tube, then the last additional hole must be cut through the radiopaque line to keep track of the most proximal hole radiographically. Silicone-based chest tubes are softer than the more rigid PVC tubes. Conventional wisdom states that the silicone tube elicits less pain for the patient given the softer structure; however, there have been no randomized trials comparing PVC and silicone tubes to confirm this.

Both chest tube types come in smaller, even small-bore sizes, while maintaining their classic chest tube configuration. They are differentiated from other small-bore tubes such as pigtail catheters in that they are not placed by the Seldinger technique (see later in this article) but by surgical tube thoracostomy like other large-bore tubes. These smaller chest tubes are used frequently in pediatric cardiothoracic surgery, and the appropriate size is based on the weight of the child in kilograms (**Table 1**).

Other types of LBCTs include spiral channel silicone tubes, or Blake drains (Ethicon, Inc, Somerville, NJ). These silicone tubes lack a hollowed out inner lumen, but have a spiral groove that is efficient for draining fluid (**Fig. 3**). The drains are flexible and malleable, and therefore the perception is that they elicit less pain for the patient. The spiral chamber, although efficient for fluid drainage, is often suboptimal for the adequate evacuation of air in the pleural space.

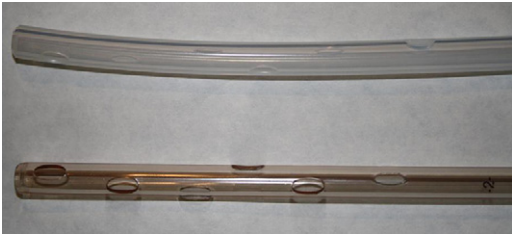


Fig. 1. Silicone Axiom (*top*) and PVC Argyle (*bottom*) 28-Fr chest tubes.

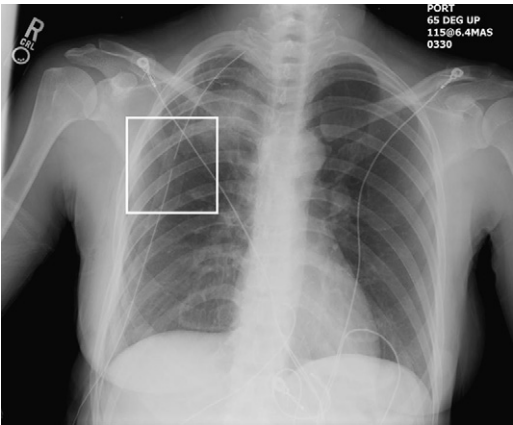


Fig. 2. Proximal hole of a 28-Fr chest tube (*box*) within the pleural space.

Function

Like all cylindrical structures, pleural tubes abide by the physics of Poiseuille’s law and the Fanning equation. For liquids, Poiseuille’s law states that flow is determined by the viscosity of the liquid, the length of the tube, and pressure changes between the ends of the tube. Flow of gas is determined similarly by the Fanning equation. Chest tubes can drain pleural fluid and air either passively or actively with negative suction generally ranging from –10 to –20 mm Hg.

In both Poiseuille’s law and the Fanning equation, small increases in the diameter of the tube lead to greater flow of fluid and air. Therefore, the larger the Fr value of a chest tube, presumably the greater the flow through the tube. However, Fr refers to the outer diameter of a chest tube. As mentioned earlier, the inner diameter can vary depending on the thickness of the tube wall. In addition, patient variables may differ including the consistency and quality of pleural clots and pleural debris, and the presences or absence of free-flowing anatomy of the pleural space, leading to heterogeneity of pleural pressure.

Table 1 Estimated chest tube size in pediatric patients based on patient weight	
Patient Weight (kg)	Chest Tube Size (Fr)
<3	8–10
3–5	10–12
6–10	12–16
11–15	17–22
16–20	22–26
21–30	26–32

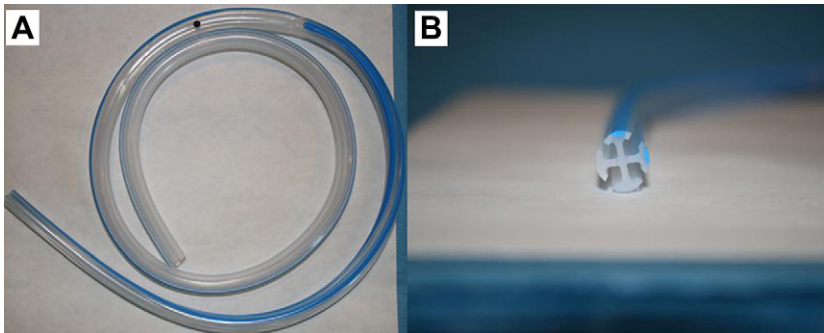


Fig. 3. (A) 24-Fr Blake drain. (B) Cross-section of a 24-Fr Blake drain.

Indications

The indications for placement of a LBCT are myriad. The British Thoracic Society guidelines give the following indications for chest drain insertion:

- Pneumothorax
- Malignant pleural effusion
- Empyema
- Hemothorax
- Postoperative management of chest cavity

LBCTs are effective for all these indications.¹ However, for stage III fibrinopurulent empyema, the high viscosity and organized characteristics of the effusion make chest tubes ineffective, and surgical lung decortication is necessary. With regard to hemothorax, the Advanced Trauma Life Support Recommendations (ATLS) state that a 36-Fr LBCT should be used for drainage of hemothorax.² In a similar setting in postoperative cardiac surgery, Shalli and colleagues³ surveyed 106 cardiothoracic surgeons and found that 86.8% of the respondents worry that a 20-Fr tube has a higher potential to become clogged with a clot than a larger diameter 36-Fr tube. However, Inaba and colleagues⁴ found no difference in the rate of retained hemothorax or even postprocedural pain when comparing LBCTs of 36 to 40 Fr with LBCTs of 28 to 32 Fr in a trauma population requiring open chest tube drainage. Sakopoulos and colleagues⁵ found no difference in the need for mediastinal exploration and subsequent additional pleural drainage procedures in patients undergoing cardiac surgery with postprocedure 19-Fr Blake drains compared with traditional LBCTs of 28 to 36 Fr.

SBCTS

Definition

Historically, LBCTs have been used to evacuate pleural fluid and air because of their resistance to

clogging, perhaps at the cost of significant discomfort for the patient both during insertion and while in situ. However, with the development of SBCTs, many pleural conditions can be treated with little difference in clinical efficacy. Typically, SBCTs range from 6 to 19 Fr; 6-Fr tubes are used for pediatric patients. Although randomized trials comparing LBCTs and SBCTs are limited, in recent years, the use of the SBCTs has become more widespread. SBCTs are now routinely used for drainage of pneumothorax, malignant and benign pleural effusion, and empyema.

Types

SBCTs come in many varieties. The most common tubes are pigtail catheters, which curl after removal of a rigid insert (**Fig. 4**). The curved nature of the tube prevents dislodgement of the drain. Pigtails come in varying sizes and are made by several companies including Cook Medical Inc. (Bloomington, IN), C.R. Bard Inc. (Covington, GA), and Boston Scientific Corp. (Natick, MA). Pneumothorax catheter kits are commercially



Fig. 4. (A) Cook pigtail catheter with rigid insert and (B) after removal of insert.

available from Cook Medical ranging from 10 to 14 Fr. They can be placed over trocars or by the Seldinger technique; these kits are designed for simple pneumothoraces.

Trocar catheters from Covidien and Utah Medical Products Inc. (Midvale, UT) are also available. The trocar catheters are single-use devices composed of a sharp or blunt trocar and a clear catheter made of either PVC or silicone. These catheters should be used with caution as acknowledged difficulties and nuances with insertion make the complication rate with these tubes as high as 25%.⁶ Previous reports suggest that use of a blunt trocar rather than a sharp trocar may decrease complications; moreover blunt dissection into the chest before tube insertion allows for the safest tube placement when using a trocar chest catheter.⁶

The use of modified single lumen central lines as pleural catheters for both air and fluid drainage has also been described.^{7,8} Both groups describe the use of 14-gauge single lumen central venous catheters modified with additional holes in the distal catheter to facilitate drainage. These catheters are placed into the pleural space using a sterile Seldinger technique with good results and lower cost than other pneumothorax kits. It is necessary to use a connector device to connect these single lumen catheters to suction drainage or Heimlich valves; either stopcocks or a Leur-lock connector can be used.

Indwelling pleural catheters are commonly used in the setting of malignant pleural effusions because they result in excellent symptomatic relief of dyspnea for patients and allow for outpatient management.⁹ The most common indwelling pleural catheter is the PleurX catheter (Denver Biomaterials Inc, Golden, CO), which is a 15.5-Fr catheter that is tunneled through the skin and then into the pleural space. A one-way valve at the end of the catheter can be connected to vacuum containers to allow for patient-controlled evacuation of fluid. These catheters facilitate drainage of effusions as well as sclerosing therapies, which are helpful in the outpatient management of malignant effusions.

Function

Critics of SBCTs have proposed that smaller tubes are more likely to clog or kink and become non-functional, limiting their clinical efficacy. In a study from Duke University comparing 3 sizes and brands of small-bore tubes, flow rates were analyzed using both water and oil.¹⁰ Catheters from Cook, C.R. Bard, and Boston Scientific were compared. There were no significant differences

in flow rates (1.5–2.2 mL/s/s) for 8-Fr tubes between the 3 brands. For the 10-Fr tubes, 2 brands, Bard and Boston Scientific, had significantly faster flow rates than Cook (4.0, 4.1 mL/s/s vs 2.5 mL/s/s, $P<.05$). For the 12-Fr catheters, Bard showed significantly faster flow when compared with the other 2 brands (6.1 mL/s/s vs 4.3, 4.4 mL/s/s, $P<.05$). In this study, Macha and colleagues¹⁰ found no differences in susceptibility to kinking or problems with patency between the brands or sizes. They did find that the presence of a stopcock significantly impaired flow through the catheter regardless of catheter size, which they attributed to the decrease in internal diameter between the standard stopcocks (1.3–1.5 mm) and the tubes themselves (1.7–3.2 mm). The impairment of flow caused by stopcocks is relevant clinically as the smaller tubes are frequently connected with stopcocks to facilitate flushing of the catheter. For this reason, we advocate the use of a large device stopcock rather than a small one to avoid the discrepancy between internal diameters.

In addition to serving as a conduit for drainage of fluid and air, pleural catheters are also used to facilitate pleurodesis in the setting of malignant effusions. Conventional wisdom dictates that SBCTs do not allow for adequate pleurodesis, because tube size limits efficacious delivery of sclerosing therapies. However, it has been demonstrated that tube size does not have any influence on recurrence rates after sclerosis with talc, tetracycline, bleomycin, or interferon in patients with malignant effusions.¹¹

Indications

Indications for SBCTs mirror those for LBCTs, including pneumothorax, hemothorax, empyema, malignant pleural effusion, and management of the postoperative chest space. The British Thoracic Society guidelines recommend that small-bore tubes be used where possible because of increased patient comfort except in cases of acute hemothorax.¹ The concern about SBCTs in cases of hemothorax relates to the potential for inadequate drainage resulting in retained hemothorax, and the inability to identify ongoing hemorrhage.⁴ Yi and colleagues¹² studied 407 patients who were randomized to chest drainage using either a 16-gauge single lumen central venous catheter (CVC) or conventional chest tubes for traumatic hemothorax. The study found no differences between the groups for indwelling time or severe complications. The identification of progressive hemothorax was possible in the study using changes in pulse rate, blood pressure, and

decreased hemoglobin in combination with drainage output. Patients in the study with the CVCs were able to drain more than 1000 mL/h through the CVC. The investigators concluded that the combination of clinical change in vital signs and chest drainage can be used to identify ongoing hemorrhage in patients who have CVCs placed for traumatic hemothorax. Although the support in the medical literature for SBCT use in the setting of hemothorax is compelling, higher powered studies are needed before this practice can be recommended.

The use of SBCTs is increasing as studies continue to demonstrate decreased pain and discomfort, as well as equivalent efficacy for drainage of pneumothorax. In a study of trauma patients with pneumothorax treated with pleural catheters (14 Fr) or chest tubes, Kulvatunyou and colleagues¹³ showed no difference in the duration of intubation, the need for mechanical ventilation, or insertion-related complications between the 2 types of tubes. There was a trend toward a higher tube failure rate in the patients who received an SBCT (11% vs 4%, $P = .06$), but this was not significant. Other series report an 81% success rate for drainage of pneumothorax when using an 8-Fr pleural catheter.¹⁴

Pneumothorax as an indication for SBCT is intuitive, but their use in empyema is under scrutiny because of concerns about the effectiveness of the tubes in the setting of high viscosity pleural fluid or loculated collections. In 82 patients with effusion ($n = 30$) or empyema ($n = 52$) involving 93 SBCTs, Keeling and colleagues¹⁵ found that 19% of patients with empyema went on to require surgical decortication. The patients with empyema were also more likely to require urokinase to maintain tube patency than patients with pleural effusion (51% vs 6%, $P < .05$).¹⁵ Rahman and colleagues¹⁶ reported no difference in the need for surgery among patients treated with pleural catheters for empyema when tube sizes were compared. They did find an increase in pain scores in patients who received a pleural catheter larger than 20 Fr.¹⁶ In the setting of empyema, the use of SBCTs for definitive therapy should be approached with caution. There should be a low threshold for the placement of additional drains or surgical intervention in patients with empyema who do not demonstrate clinical and radiographic improvement.

COMPARATIVE EFFECTIVENESS OF LARGE-BORE TUBES VERSUS SMALL-BORE TUBES

With advances in radiographic guidance, including computed tomography and ultrasonography, and

the relative ease of insertion, the use of SBCTs has become more prevalent. With the increase in the use of SBCTs, it is important to understand the strengths and weaknesses of both types of tubes for various indications. Unfortunately, large multi-institution randomized studies comparing the clinical efficacy, complications, cost, and patient satisfaction with large-bore and small-bore tubes do not exist. Therefore, interpretations of comparisons between the 2 types must be made with care.

Pain

In general, it is thought that SBCTs are less painful both during insertion and while indwelling because there is less disruption and irritation of the intercostal space. However, there is little data to directly determine the effect of tube size on perceived pain. In a study of 52 drains inserted in 44 patients ranging from 12 to 20 Fr, the visual analog scale (VAS) scores for patient pain showed no significant correlation with the size of the tube.¹⁷ In a study of trauma patients receiving chest tubes of 28 to 40 Fr, the VAS scores also showed no correlation with size.⁴ Horsley and colleagues¹⁷ found no difference in the amount of lidocaine for local analgesia used between sizes of tube inserted in their series of SBCTs. From these data, it is difficult to draw a definitive conclusion on superiority of pain with regard to SBCTs and LBCTs.

Complications

As with any invasive procedure, complications can occur during chest tube placement and while they are indwelling. Some of the complications described for chest tubes include malposition, bleeding, infection, pulmonary complications, inadvertent removal, occlusion, or failure of therapy. In their series of trauma patients, Inaba and colleagues⁴ found no differences in the overall complication rate, pneumonia after tube placement, infection, or failure of drainage when they compared tube sizes of 28 to 32 Fr versus 36 to 40 Fr. Their overall complication rate was 15.6% and retained hemothorax rate was 11.3%. In a separate study of 122 tubes inserted into 75 patients, a malposition rate of 30% was found for tube sizes of 24 to 32 Fr and use of a trocar was found to be a predicting factor for malposition.¹⁸ In Horsley and colleagues¹⁷ series with drains of 12 to 20 Fr inserted over a 10-month period, there were no malposition complications using the Seldinger technique for insertion. There was a case of empyema after a drain was inserted for a malignant effusion in 1 patient, but no other

infectious complications were reported.¹⁷ The rate of empyema was 4.4% in the trauma patients who underwent placement of tubes of 28 to 40 Fr, with no differences related to the size of tubes.⁴ Avoidance of the trocar insertion technique may result in fewer complications related to malpositioning for either large-bore or small-bore tubes. Based on these data, the overall complication rates for large-bore and small-bore tubes seem to be similar.

Effectiveness

In Horsley and colleagues' ¹⁷ series, the therapeutic success rate was only 63%, mainly due to drain failure, drain blockage, or dislodgement, but this did not vary by size. The small drains were more successful when used for pneumothorax and malignant or parapneumonic effusions than when used for empyema ($P < .025$).¹⁷ In contrast, in the series of trauma patients who received LBCTs, the procedure success rate was 88.7% when used for traumatic hemothorax.⁴ These data suggest that indication for drain placement may be an important factor for decisions about tube size. For empyema it is possible to use SBCTs for drainage and evacuation, but there should be a low threshold for placement of additional drains or proceeding with definitive operative management.

Cost

Tubes that are placed at the bedside using either blunt dissection or insertion or the Seldinger technique cost less than tubes placed under radiographic guidance in a formal interventional radiographic suite. However, there is a risk of malposition when tubes are placed without radiographic guidance, which may add more to the overall cost of treatment. Several factors can contribute to the cost of chest drainage systems including the tubes themselves, suction drainage systems, the use of commercially prepared kits, and the use of reusable instruments from sterile supply. Further studies of cost analysis and effectiveness are needed before definitive conclusions can be drawn based on tube size.

TECHNIQUES FOR PLACEMENT

Placement of LBCTs

Placement of LBCTs is referred to as tube thoracostomy. A tube thoracostomy can be performed at the bedside with minimal patient discomfort if placed properly and with attention to detail. As with any surgical procedure, the first step is logical patient positioning. If, for example, the LBCT is

placed in the left pleural space, the left arm is abducted behind the patient's head. A roll is placed behind the left flank, to elevate the patient's side 30° to 45°. Even with normal oxygen saturation, the patient should be given supplemental oxygen. The contralateral arm should be available for intravenous access and blood pressure monitoring. Key external anatomic landmarks are the ipsilateral nipple, tip of the scapula, the costal margin, and the anterior superior iliac spine. LBCTs should be placed anterior to the line of the anterior superior iliac spine or the patient may lie on the chest tube and kink and occlude it when supine; lying on the chest tube can worsen pain. Often LBCTs are placed in the fifth intercostal space in the midaxillary line. If the tube is placed for effusion, it can be placed in a lower intercostal space, but care must be taken to avoid over penetrating through the diaphragm into the peritoneal cavity; the diaphragm, depending on the respiratory cycle, can rise as high as the third intercostal space in some patients.

Local analgesia is achieved with 1% to 2% lidocaine. The appropriate rib is determined and, using a 22-gauge needle, the periosteum is infiltrated with lidocaine. The neurovascular bundle is at the inferior edge of the rib. The needle is passed over the superior edge of the rib while pulling back on the plunger. The needle is advanced until the air or fluid in question is aspirated. The anesthetic is not injected at this point, as it will just disseminate ineffectively into the pleural space. Once air or fluid is aspirated, the needle is slowly withdrawn still pulling back on the plunger until aspiration stops. This point represents the parietal pleura, and liberal injection of anesthetic agent is performed. Afferent nerve fibers are present in the parietal pleura.

An incision of 1 to 2 cm is made over the rib. Using a hemostat, the tissue is dissected using a spreading technique until the pleural space is entered. The pleural defect is then spread widely so that a finger can easily follow the track into the pleural space. Using a finger, the lung is palpated and flimsy adhesions are broken. Thick adhesions should not be bluntly dissected as they can be highly vascular and could result in significant postprocedure bleeding. The LBCT is then inserted using a curved clamp. The clamp is advanced posteriorly and apically. The clamp is released, the tube is inserted, and rotated contralateral to the mediastinum to avoid insertion into the major fissure. It is important to confirm manually that the tube is indeed in the pleural space, because it is easy to mistakenly insert the chest tube extrapleurally, especially in patients with generous adipose tissue (**Fig. 5**).

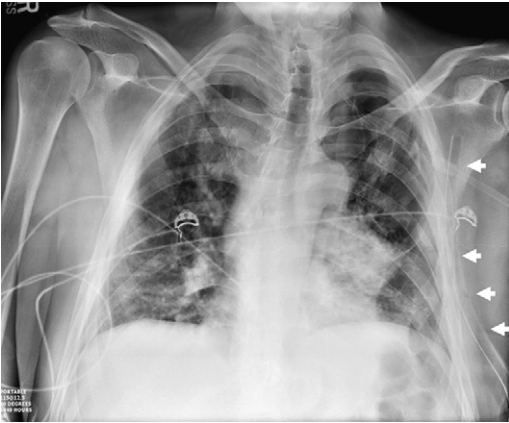


Fig. 5. 28-Fr chest tube placed extrapleurally (arrows).

Placement of SBCTs

There is anecdotal consensus that SBCTs are less painful than larger tubes, both on insertion and while indwelling. The decreased pain felt during the indwelling period is largely believed to be secondary to the idea that the catheter is small enough not to disturb the next cephalad rib and impinge on the adjacent intercostal nerve. However, the pain on insertion is largely related to the degree of pressure and force needed to gain entry into the chest and the amount of local analgesia administered during insertion. When we place SBCTs at the bedside, we use generous local 1% to 2% lidocaine based on the weight of the patient in both the subcutaneous space and parietal pleura. Adequate analgesia serves 2 purposes: (1) to decrease irritation caused by the dilators and wires used when inserting a tube with the Seldinger technique; (2) to ensure that the pleural space has been entered by confirming aspiration of air into a syringe filled with local anesthetic. Once adequate analgesia has been established, proceed with tube placement.

SBCTs should be placed at the top of a rib and guided over the rib similar to LBCTs to avoid damage to the neurovascular bundle. SBCTs are typically placed in the second intercostal space along the anterior axillary line, especially when being used for drainage of pneumothorax. However, SBCTs can be placed anywhere into the pleural space. When tubes are being placed under radiographic guidance, care should be taken to place the tube in a position to allow optimal function with attention paid to patient comfort. When placing tubes in a dependent position for fluid drainage, it is important to consider body habitus and position because those factors may affect patient comfort and tube patency.

An additional consideration with SBCTs is the ease with which they can become dislodged, particularly during the placement process. With some kits, it is possible to connect the tube to the suction apparatus or Heimlich valve before placement into the pleural cavity, which can help with patient discomfort during placement as well, because tube manipulation is minimized. This setup is not useful for all patients, and is not recommended when it is necessary to sample pleural fluid for diagnosis.

The ability to place SBCTs with radiographic guidance is a significant advantage over LBCTs. Ultrasonography has been shown to be a safe adjunct to traditional Seldinger or blunt dissection techniques for placement of SBCTs with a low procedure-related complication rate.¹⁹ Transthoracic ultrasonography is also useful for accurate localization and surveillance of pleural effusions, which can not only guide placement but also help guide sclerosing therapies of residual collections.²⁰ When available, we recommend the use of ultrasonography during placement of SBCTs and for surveillance of the pleural cavity.

SUMMARY

The indications for SBCTs continue to increase, as does their use for upfront drainage of pleural conditions. SBCTs can be as effective as LBCTs for pneumothorax, basic effusions, and simple empyema, with the exception of hemothorax and complex empyema. SBCTs should be considered for first-line drainage therapy. If not effective, then an LBCT or thorascopic surgical therapy should be the next therapeutic intervention. SBCTs are likely ineffective for complex empyema and hemothorax, and LBCTs should be considered standard first-line therapy in that setting.

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