The small (14 Fr) percutaneous catheter (P-CAT) versus large (28–32 Fr) open chest tube for traumatic hemothorax: A multicenter randomized clinical trial

Narong Kulvatunyou, MD, Zachary M. Bauman, DO, Savo Bou Zein Edine, MD, Marc de Moya, MD, Casandra Krause, MD, Kaushik Mukherjee, MD, Lynn Gries, MD, Andrew L. Tang, MD, Bellal Joseph, MD, *and* **Peter Rhee, MD***, Tucson, Arizona*

INTRODUCTION: The traditional treatment of traumatic hemothorax (HTX) has been an insertion of a large-bore 36- to 40-Fr chest tube. Our previous single-center randomized controlled trial (RCT) had shown that 14-Fr percutaneous catheters (PCs) (pigtail) were equally as effective as chest tube. We performed a multicenter RCT, hypothesizing that PCs are as equally effective as chest tubes in the management of patients with traumatic HTX (NCT03546764).

METHODS: We performed a multi-institution prospective RCT comparing 14-Fr PCs with 28- to 32-Fr chest tubes in the management of patients with traumatic HTX from July 2015 to September 2020. We excluded patients who were in extremis and required emergent tube placement and those who refused to participate. The primary outcome was failure rate, defined as a retained HTX requiring a second intervention. Secondary outcomes included daily drainage output, tube days, intensive care unit and hospital length of stay, and insertion perception experience (IPE) score on a scale of 1 to 5 (1, tolerable experience; 5, worst experience). Unpaired Student's *t* test, χ^2, and Wilcoxon rank sum test were used with significance set at $p < 0.05$.

RESULTS: After exclusion, 119 patients participated in the trial, 56 randomized to PCs and 63 to chest tubes. Baseline characteristics between the two groups were similar. The primary outcome, failure rate, was similar between the two groups (11% PCs vs. 13% chest tubes, $p = 0.74$). All other secondary outcomes were also similar, except PC patients reported lower IPE scores (median, 1: "I can tolerate it"; interquartile range, 1–2) than chest tube patients (median, 3: "It was a bad experience"; interquartile range, 2–5; $p < 0.001$).

CONCLUSION: Small caliber 14-Fr PCs are equally as effective as 28- to 32-Fr chest tubes in their ability to drain traumatic HTX with no difference in complications. Patients reported better IPE scores with PCs over chest tubes, suggesting that PCs are better tolerated. (*J Trauma Acute Care Surg.* 2021;91: 809–813.

LEVEL OF EVIDENCE: Therapeutic, level II.

KEY WORDS: Percutaneous catheter; pigtail catheter; chest tube; and hemothorax.

Traumatic hemothorax (HTX) has been traditionally managed with a large-bore (36–40 Fr) chest tube.[1] However, placing a chest tube by an open cutdown technique is always associated with significant patient's pain and discomfort. We have previously shown that a smaller caliber tube, 14-Fr percutaneous (pigtail) catheter (PC) that is placed percutaneously, is associated with less patient's pain and discomfort, for both traumatic pneumothorax (PTX)[2,3] and HTX.[4,5]

It remains a long-held belief to many clinicians that the larger the tube (the inner diameter caliber of the tube measured in French, 1 Fr = 1/3 mm),[6] the more effectively the blood will drain. However, the diameter of the tube does not limit the quantity of the fluid that can be drained, keeping the character of the fluid remains the same (unclotted blood), but the flow rate can be affected, according to the Poiseuille law (Flow α [Radius^4 $\times$ ΔPressure]/Viscosity $\times$ L).[7] However, despite that there may be a flow rate difference between PCs and chest tubes, which may or may not have any clinically relevance, we believe that the rate limiting factor is the presence of a clotted blood. Liquid form, unclotted, blood will flow through any tube size, but a clotted blood will not flow through even in a 40-Fr chest tubes.

This current study is built upon the previous work that demonstrated in both a prospective study[4,5] and a recent single-center randomized controlled trial (RCT)[8] that 14-Fr PCs are equally as effective as 28- to 32-Fr chest tubes in draining traumatic HTX. In an effort to ensure a generalizability, we performed a larger multi-institutional RCT study. We hypothesized that PCs are still as equally effective as chest tubes in the management of patients with traumatic HTX.

PATIENTS AND METHODS

This multi-institutional trial was registered with Clinica lTrials.gov (identifier, NCT3547664). Institutional review board

Submitted: January 13, 2021, Revised: February 25, 2021, Accepted: March 8, 2021, Published online: March 15, 2021.

From the Division of Acute Care Surgery, Department of Surgery (N.K., L.G., A.L.T., B.J.), University of Arizona, Tucson, Arizona; Division of Acute Care Surgery, Department of Surgery (Z.M.B.), University of Nebraska, Omaha, Nebraska; Division of Acute Care Surgery, Department of Surgery (S.B.Z.E., M.d.M.), Medical College of Wisconsin, Milwaukee, Wisconsin; Division of Acute Care Surgery, Department of Surgery (C.K., K.M.), Loma Linda University, Loma Linda, California; and Department of Surgery (P.R.), New York Medical College, Valhalla, New York.

This study was presented at the 51st Annual Western Trauma Association Scientific Meeting, February 28 to March 5, 2021, in Big Sky, Missouri.

Address for reprints: Narong Kulvatunyou, MD, Department of Surgery, Northwest Medical Center, 6200 N La Cholla Blvd, Tucson, AZ 85741; email: nkulvatunyou@gmail.com.

DOI: 10.1097/TA.0000000000003180

for each participating center reviewed the protocol and approved the study. All patients or their next of kin provided informed consent before enrollment.

Patient Inclusion and Exclusion

Patients were eligible if they were 18 years or older who suffered traumatic HTX or hemopneumothorax (HPTX) requiring drainage. For HPTX, if the HTX was small and the drainage tube was being placed primarily for the PTX, the patient was not enrolled in the study. The decision to place a tube (or catheter) was at the discretion of the treating physician, which was guided by a chest radiography and/or frequently by a computed tomography (CT) scan; however, CT scan was not required. In general, HTX volumes of >300 mL according to CT volumetric calculation[9] was used as a general guide for when to drain HTX. However, not all studied patients required or received CT scans, and we did not prespecify a specific amount of blood to be drained. The study paralleled current every day practice. Exclusion criteria included emergency placement due to hemodynamic instability (patient was in extremis as determined by treating physician and/or unable to provide consent because of the physiologic stress produced by the trauma injuries), the catheter placement in the operating room as part of the operating procedure, or the catheter placement in patients who declined to participate in the study or researcher was unable to obtain consent from either the patient or the next of kin.

Randomization and Funding Source

The randomization allocation was generated by the primary investigator (PI) institution using the internet website www.random.org to generate two integers (0, 1) in a block size of four. The assignment was then electronically sent to each participating center (co-principal investigator) in a concealed folder, only one assignment can be opened one at a time. For the PI's institution, the assignment was placed in a sealed envelope by personnel not involved in the study. The treatment assignment was for 14-Fr PCs (Cook Medical LLC, Bloomington, IN), and the control arm was 28- to 32-Fr chest tubes. Only after the patient met the inclusion criteria, agreed to participate, and consent was obtained was the envelope then opened or the electronic assignment revealed.

This study was partially funded by Cook Medical LLC. However, the sponsor had no role in study design, study conduct, site selection and participation, data collection, data interpretation, or article preparation. The corresponding author collected and had access to all data and had final responsibility for the decision to submit for publication.

Placement of PCs or Chest Tubes

Both PCs and chest tubes were inserted under sterile conditions at bedside by the attending trauma surgeon or a surgical resident under a direct supervision. Antibiotics were not routinely administered for placement of the drainage tube. One percent lidocaine was given for local anesthetic, along with an intravenous analgesic of choice for systemic analgesia. We did not standardize the dosage, quantity, or type of analgesic medication or local anesthetic to better imitate the real-life setting. Percutaneous catheters were inserted using a modified Seldinger technique at the fourth or fifth intercostal space, anterior axillary or midaxillary line. Chest tubes were inserted by the traditional cutdown method at the fourth or fifth intercostal space, midaxillary line. A chest radiography was always performed after each procedure to evaluate tube position and to confirm resolution of the HTX/HPTX. The tube was left on continued suction at −20 mm Hg. The remaining tube management and secondary interventions were left to the discretion of the rounding attending trauma surgeon. In general, at most trauma centers, trauma surgeons generally round and routinely cross-cover the patients; therefore, the management of patients with traumatic HTX/HPTX is not managed by one person but often by team approach. Given that there is no standardization of chest catheter management in current literature, this crossover allows for better imitation of real-world clinical practice and accounts for any variability present with tube management. Before the implementation of a secondary intervention for a possible retained hemothorax (rHTX), a repeated chest CT scan or ultrasound was always obtained for confirmation.

Outcome and Data Collection

Baseline characteristics were collected including age, sex, mechanism of injury (blunt vs. penetrating), number of rib fractures, presence of flail chest, Injury Severity Score, chest Abbreviated Injury Scale score, and number of days from the time of injury when the tube was inserted. We designated day 0 as immediate tube placement during an initial evaluation always in trauma bay, and anything outside this window was designated to day_1, day_2, and so forth. The primary outcome was a failure rate for the drainage catheter. Failure rate was defined as an rHTX (radiographically apparent hemothorax after tube thoracostomy) requiring additional intervention including either a second catheter insertion, a thrombolysis, or a video-assisted thoracoscopy surgery. At each participating institution, video-assisted thoracoscopy surgery was common and primarily used to manage rHTX. Secondary outcomes included initial drainage output (mL) 30 minutes after the tube was inserted; 24-hour, 48-hour, and 72-hour tube output; total tube days; insertion-related complications; ventilator days; intensive care unit length of stay; hospital length of stay; and insertion perception experience (IPE) score.

The IPE score was assessed 30 minutes after PC or chest tube insertion. The IPE score (institutionally created and not a validated score) is an ordinal scale from 1 to 5 created to capture the following patient's sentiment/experience during tube/catheter insertion:

1. It was okay, I can tolerate it, I can do it again.
2. It was okay, but I do not want to go through this again.
3. It was a bad experience for me.
4. It was a worse experience for me.
5. It was the worst experience of my life!

Each participating center entered data into a password-protected Microsoft Excel 2019 spreadsheet (Microsoft, Microsoft Excel 2019, Richmond, WA) using a prespecified collection datasheet provided with deidentified data, and the final results were submitted to the PI for the tabulation and final analysis at the conclusion of the study.

STATISTICAL ANALYSIS

We tested our hypothesis that PCs would be noninferior to chest tubes with respect to the primary outcome, failure rate. We

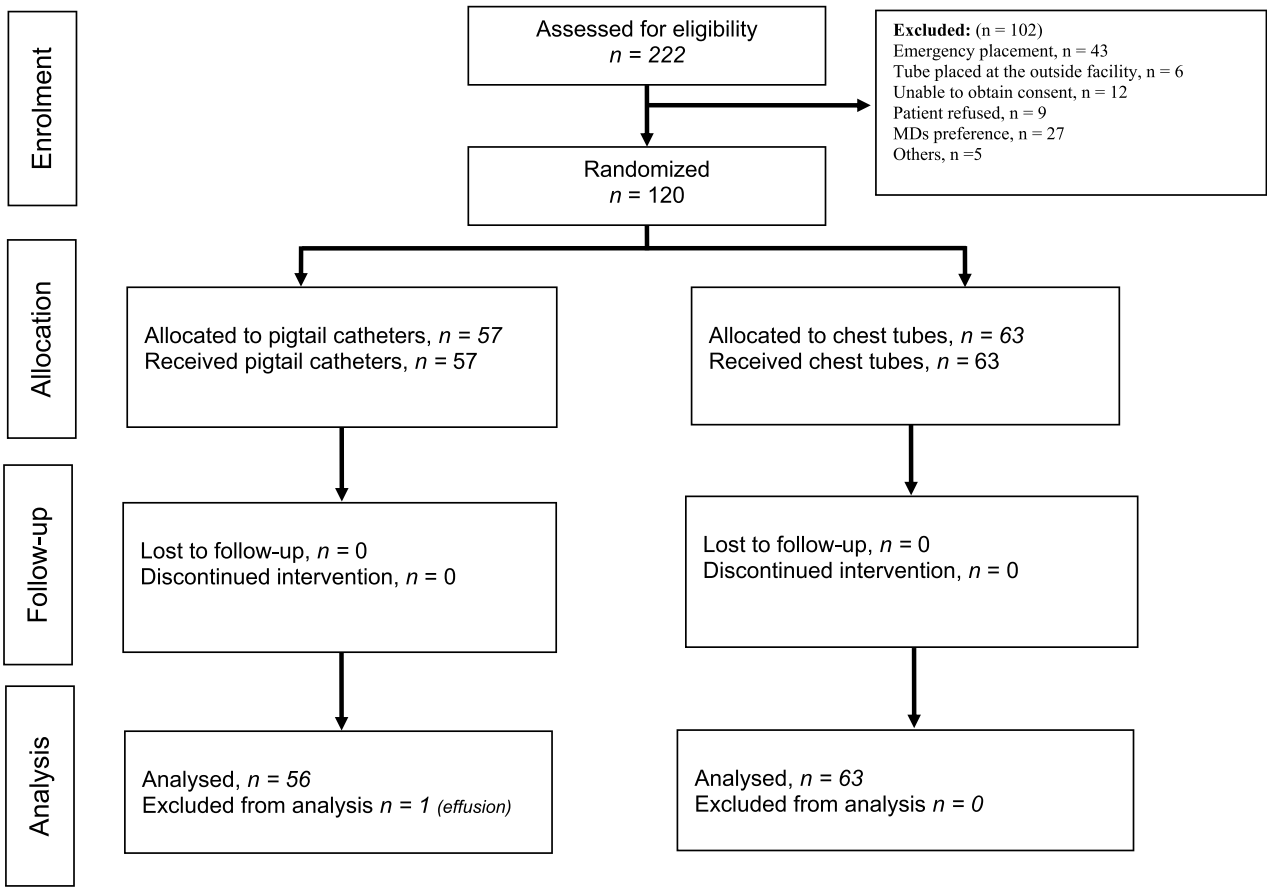

Figure 1. Consolidated standards of reporting trials diagram.

prespecified a noninferior margin of 15% based on previous failure rates for chest tubes of 30%[4,5,9] and for PCs of 15%.[4,5] We estimated the sample size to be 95 patients each arm with 80% power and 1-sided α of 0.05. However, after a prolonged period of enrollment, coupled with an interruption by the coronavirus 2019 outbreak, we performed an interim analysis with the primary outcome still met noninferiority parameter. We then decided to conclude our study.

Continuous variables were expressed as mean ± SD or median (interquartile range [IQR]). Categorical variables were expressed as proportions or percentages. For between-group comparisons, Student's *t* test was used for continuous normally distributed data, the Wilcoxon rank sum test for nonnormally distributed data, and χ^2 test for categorical data. For statistical analysis, a Stata version 14 (StataCorp LLC, College Station, TX) was used. Two-sided $p < 0.05$ was considered statistically significant.

RESULTS

From July 2015 to September 2020, 222 patients were screened, of which 120 were enrolled. Those excluded had similar age (50 ± 22 years vs. 55 ± 18 years, $p = 0.07$), were majorly male (92% vs. 82%, $p = 0.003$), and suffered more penetrating trauma (39% vs. 19%, $p = 0.03$), compared with those enrolled. Of those enrolled, 57 were randomized to PCs and 63 to chest tubes. One patient from PC was excluded from the final analysis after enrollment because the patient was found to not have HTX rather a chronic pleural effusion, yielding 56 patients for PCs and 63 for chest tubes for the final analysis (Fig. 1). There were no significant differences in the baseline characteristics between the two groups (Table 1) as well as stratified by sites (Table 2). The majority of mechanisms of injury for both groups were blunt, and the days from injury when the tube was inserted were similar. The primary outcome, failure rate (Table 3), was not statistically

TABLE 1. Demographic Data and Baseline Characteristics

	Pigtail Catheters (n = 56)	Chest Tubes (n = 63)	*p*
Age, mean ± SD, y	56 ± 17	54 ± 19	0.50
Sex (male), %	84	81	0.67
Blunt, %	87	75	0.08
ISS, mean ± SD	17.8 ± 6.8	17.3 ± 6.8	0.71
c-AIS score, median (IQR)	4 (3, 4)	4 (3, 4)	0.89
No. rib fractures, mean ± SD	4.4 ± 3.5	4.5 ± 3.6	0.50
Flail (yes), %	16	10	0.28
Days from injury tube inserted, median (IQR)	2 (1, 5)	1 (1, 2)	0.21

c-AIS, chest Abbreviated Injury Scale; ISS, Injury Severity Score.

TABLE 2. Demographic Data and Baseline Characteristics Stratified by Sites

	Pigtail Catheters	Chest Tubes	*p*
Site 1	**n = 37**	**n = 43**	
Age, mean + SD, y	56 ± 17	53 ± 18	0.32
Sex (male), %	81	90	0.21
Blunt, %	84	67	0.09
ISS, mean ± SD	17.5 ± 6.6	16.1 ± 7.1	0.38
Site 2	**n = 14**	**n = 13**	
Age, mean ± SD, y	54 ± 19	58 ± 18	0.59
Sex (male), %	93	54	0.02
Blunt, %	93	92	0.96
ISS, mean ± SD	18.4 ± 7.4	19.5 ± 6.4	0.68
Site 3	**n = 3**	**n = 5**	
Age, mean ± SD, y	46 ± 18	50 ± 28	0.84
Sex (male), %	67	80	0.67
Blunt, %	100	80	0.41
ISS, mean ± SD	22.3 ± 6.5	21.8 ± 3.2	0.88
Site 4	**n = 2**	**n = 2**	
Age, mean ± SD, y	69 ± 5	55 ± 7	0.14
Sex (male), %	100	50	0.25
Blunt, %	100	100	NS
ISS, mean ± SD	13.0 ± 5.0	18.0 ± 2.8	0.31

ISS, Injury Severity Score; NS, nonsignificant.

different between the two groups (11% PCs vs. 13% chest tubes, $p = 0.74$). Initial and 24-hour output favored PCs, but the daily output was eventually the same at 48 hours and 72 hours. When analyzing the IPE score, however, PC patients reported a lower median IPE score (median, 1, "I can tolerate it"; IQR, 1–2) than chest tube patients' score (median, 3, "It was a bad experience"; IQR, 2–5; $p < 0.001$). All other remaining secondary outcomes were similar between groups (Table 3).

There were two insertion-related complications: one was a bleeding from PC necessitated a thoracotomy, but the patient did well, and one was an extrapleural position from chest tube placement required another tube placement. There were two deaths, one from each group. The one from the PC group died from a major pulmonary embolism on postinjury day 10 and the tube had already been removed. The one from the chest tube group died from a nontrauma-related cause of death at an outside institution.

DISCUSSIONS

In this multi-institution RCT study, we demonstrated that 14-Fr PCs were equally as effective as 28- to 32-Fr chest tubes in the management of patients with traumatic HTX as defined by our primary outcome, failure rate. This finding is similar to our previous single-center study finding,[8] but the baseline characteristics in this multi-institutional RCT became much more closely matched as the study sample size grew from 43 patients to 119 patients. Similar to all previously published PCs for HTX studies,[4,5,8] PCs were used in nonextremis and nonemergent placements, as most clinicians still feel that chest tubes can be placed with much more expedient speed and clinician's comfort than PCs. However, the authors have several anecdotal experiences placing PCs in emergency situations, and this would be the subject of future research including refinement of PC instrumentation for quicker insertion.

If the effectiveness between PCs and chest tubes for draining the blood is not any different, why then should clinicians consider using PCs as opposed to chest tubes? Few clinicians, especially trauma surgeons, would ever personally experience real life pain and agony that patients must go through during chest tube placement. The PI had several friends and family who had shared their personal painful experiences during chest tube insertion, and therefore, the PI has tried to answer this clinical question regarding tube insertion-related pain by comparing the pain of having PCs versus chest tubes placement in the RCT study for patients with traumatic PTX.[3] In that study, we found that patients had less pain associated with PCs than chest tubes on days 1, 2, and 3. However, we did not capture the pain assessment while patients were going through the procedural tube insertion. Therefore, in the current study, we created our own institutional score that we termed IPE scores ranging from 1 to 5, with 5 being the worst encountered experience. Although realizing that IPE score, like most pain scores, is subjective and has never been validated, it attempted to provide the framework to capture patient experiences between two different procedures. We found that PC patients reported a lower median IPE score compared with chest tube patients (1 vs. 3, $p < 0.001$), supporting our notion that patients might prefer PCs over chest tubes if all else were equal. We believe that this was the first study that attempted to compare patient's descriptive experience between two different procedures.

In this study, we reported a failure rate of 11% and 13%, somewhat lower than a 31% to 33% failure rate quoted in previous literature,[9–11] including 30% failure rate quoted in the most recent Eastern Association for the Surgery of Trauma Multi-institutional Trial.[12] This difference may be due to the difference in our study population baseline characteristics from those previously published, as we excluded emergent/extremis patients who might be sicker and more severely injured, as well as patients who might have other system injuries that required them to have prolonged ventilator and intensive care unit length of stay, among others. It

TABLE 3. Comparison of Outcomes

	Pigtail Catheters (n = 56)	Chest Tubes (n = 63)	*p*
Failure rate, n (%)	7 (11)	8 (13)	0.74
Initial output, median (IQR), mL	600 (375–1,037)	400 (250–650)	0.005
24 h	930 (600–1,350)	685 (450–1,000)	0.05
48 h	150 (60–310)	180 (80–300)	0.77
72 h	45 (0–200)	130 (0–272)	0.28
Tube days, median (IQR), d	4 (3–6)	5 (3–7)	0.31
IPE score, median (IQR)	1 (1–2)	3 (2–5)	<0.001
VATS, %	7	5	0.58
Ventilator day, median (IQR)	0 (0–2)	0 (0–0)	0.13
ICU day, median (IQR)	2.5 (0–3.5)	2 (0–4)	0.28
Hospital length of stay, median (IQR), d	8.5 (5.5–15)	8 (5–12)	0.30

ICU, intensive care unit; VATS, video-assisted thoracoscopy.

is interesting, however, in this prior Eastern Association for the Surgery of Trauma study,[12] that the amount of HTX was found to be a significant predictor of developing an rHTX and the average amount in those who developed an rHTX was 191 mL, compared with our studied population who had a mean HTX of 612 mL. Certainly, there are other risk factors for the development of rHTX than just the initial amount of blood in the hemithorax.

The significant limitation of our study was that we did not reach the planned study sample size. This study took 4 plus years to complete and placed a lot of burden on personnel and resources. Even at our own institution which has adopted PC usage since 2009, it still took significant time for some of our existing faculty to accept that PCs should be used for HTX drainage. Furthermore, our own division personnel have gone through some changes, further slowing down the process of getting everyone through the learning curve for placing PCs. A few participating institutions joined the study 1 or 2 years after initiation, and even then, it took them some time to get institutional review board approval and start enrolling patients. Then, in the beginning of 2020, the coronavirus 2019 pandemic halted most clinical research. As a result, we decided to close the study prematurely before reaching our goal. Despite this decision, we still feel that the sample size was robust enough, and we were still able to demonstrate noninferiority between PCs and chest tubes for the drainage of traumatic HTX. Also, as mentioned previously, we recognized that the IPE score is subjective and nonscientifically created, and has never been validated in any prior studies.

In conclusion, in this multi-institution RCT study, we found that there was no difference in terms of the failure rate between 14-Fr PCs and large-caliber (28–32 Fr) chest tubes in their ability to drain traumatic HTX. We also found that PC patients reported a better tube-insertion experience, meaning less pain and agony than chest tube patients. We suggest that, if more institutions would consider adopting PC for HTX drainage in a nonemergency setting and report their institutional experiences, more knowledge can be gained and shared among clinicians.

AUTHORSHIP

N. K., Z. M. B., M. d. M., and P. R. designed the study and searched the literature. N. K., Z. M. B., S. B. Z. E., M. d. M., C. K., and K. M. collected the data. N. K. prepared the article. N. K., Z. M. B., and M. d .M. reviewed the article. All other others participated in the data interpretation and critical review.

DISCLOSURE

The authors declare no conflicts of interest. This study was partially funded by Cook Medical LLC; however, the sponsor had no role in the study design, data collection, data analysis, and the content of the article.

REFERENCES

1. Livingston DH, Hauser CJ. Chest wall and lung. In: Moore EE, Feliciano DV, Mattox KL, eds. *Trauma*. 6th ed. New York, NY: McGraw-Hill; 2008: 525–552.
2. Kulvatunyou N, Vijayasekaran A, Hansen A, Wynn JL, O'Keeffe T, Friese RS, Joseph B, Tang A, Rhee P. Two-year experience of using pigtail catheters to treat traumatic pneumothorax: a changing trend. *J Trauma*. 2011;71(5):1104–1107.
3. Kulvatunyou N, Erickson L, Vijayasekaran A, Gries L, Joseph B, Friese RS, O'Keeffe T, Tang TL, Wynne JL, Rhee P. Randomized clinical trial of pigtail catheter versus chest tube in injured patients with uncomplicated traumatic pneumothorax. *Br J Surg*. 2014;101:17–22.
4. Kulvatunyou N, Joseph B, Friese RS, Green D, Gries L, O'Keeffe T, Tang AL, Wynne JL, Rhee P. 14 French pigtail catheters placed by surgeons to drain blood on trauma patients: is 14-F too small? *J Trauma Acute Care Surg*. 2012;6:1421–1425.
5. Bauman ZM, Kulvatunyou N, Joseph B, Jain A, Friese RS, Gries L, O'Keeffe T, Tang AL, Vercruysse G, Rhee P. A Prospective Study of 7-year experience using percutaneous 14-French pigtail catheters for traumatic hemothorax/hemopneumothorax at a level-1 trauma center: size still does not matter. *World J Surg*. 2018;42:107–113.
6. Iserson KV. J.-F.-B. Charrière: the man behind the "French" gauge. *J Emerg Med*. 1987;5(6):545–548.
7. Whitaker S. *Introduction to Fluid Mechanics*. Englewood Cliffs, NJ: Prentice-Hall; 1968:61.
8. Bauman ZM, Kulvatunyou N, Joseph B, Gries L, O'Keeffe T, Tang AL, Rhee P. Randomized clinical trial of 14-French (14F) pigtail catheters versus 28-32F chest tubes in the management of patients with traumatic hemothorax and hemopneumothorax. *World J Surg*. 2021;45(3):880–886.
9. Dubose J, Inaba K, Demetriades D, et al. Management of post-traumatic retained hemothorax: a prospective, observational, multicenter AAST study. *J Trauma*. 2012;72:11–22.
10. Kumar S, Rathi V, Rattan A, Chaudry S, Agarwal N. VATS versus intrapleural streptokinase: a prospective, randomized, controlled clinical trial for optimum treatment of post-traumatic residual hemothorax. *Injury*. 2015; 46(9):1749–1752.
11. Mowery NT, Gunter OL, Collier BR, Diaz JJ, Haut E, Hildreth M, Holevar M , Mayberry J, Streib E. Practice management guidelines for management of hemothorax and occult pneumothorax. *J Trauma*. 2011;70(2):510–518.
12. Prakash PS, Moore SA, Rezende-Neto JB, et al. Predictors of retained hemothorax in trauma: results of an Eastern Association for the Surgery of Trauma multi-institutional trial. *J Trauma Acute Care Surg*. 2020;89:679–685.