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Trocar *vs.* Seldinger small bore pleural drains: does the technique influence the outcomes? A prospective single-centre study

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Abstract. – OBJECTIVE: The aim of this study is to compare two positioning techniques of 12-French (Fr) thoracic drains in terms of efficacy, safety, and patient comfort.

PATIENTS AND METHODS: This is a prospective, non-randomized, competitive, non-inferiority study comparing the Seldinger *vs.* Trocar technique. The primary endpoint was an analysis of the factors that led to unsuccessful drainage positioning. Between the two groups, clinical variables, procedure times, pain, and complications were compared.

RESULTS: Seventy-two patients were enrolled in group 1 (Seldinger) and 45 in group 2 (Trocar). The mean procedural time was 7.93±3.02 min *vs.* 7.09±3.67 min, respectively (*p*: 0.33). The mean VAS for procedural pain was 2.22±1.47 *vs.* 2.80±1.88, *p*: 0.07, and the mean at day 2 was 3.6±1.2 in the SBWGD group *vs.* 2.7±1.1 in the Unico Group (*p*: 0.04). There was no difference in terms of complications, residual effusion, and pneumothorax at the first post-procedural chest X-ray. Four days after the procedure, the drain removal rate was 11.6% in group 1 *vs.* 25% in group 2 *p*: 0.063). The chest tube was removed after a mean period of 8.87±7.20 days after resolution of pleural effusion or tube dislodgement (7 cases in group 1 *vs.* 11 in group 2, *p*: 0.053).

CONCLUSIONS: The two techniques resulted in comparable pain and complication rates. Both drains are well-tolerated and efficient at draining pleural effusion, with very low rates of complications and failure. We recommend inserting a longer tube for patients who require chest drainage for an extended period of time.

Key Words:
Pleural effusion, Chest drain, Thoracic surgery.

Introduction

Chest tube insertion is one of the most frequent surgical procedures, performed to treat pneumothorax or pleural effusion[1]. In particular, pleural effusion drainage represents a not negligible practice in elective and emergency settings, usually performed by different specialists on several operative units[1,2]. In most cases, the main cause of pleural effusions is neoplastic, considering that in the United States the incidence of malignant pleural effusion is approximately 150,000 cases per year[3,4] and the management of these patients may require drainage as the initial step, followed by eventual surgical or medical pleurodesis. As chest tubes can be classified as small-bore chest tubes (diameter less than 20 Fr) or large-bore tubes (diameter >20 Fr), the optimal chest tube calibre is still a matter of contention. Currently, large-bore drains are indicated specifically in cases of hemothorax, pneumothorax with a high risk of massive air leak, empyema or in all those situations with a high risk of tube obstruction[5,6].

On the contrary, small-bore tubes are now preferred for the treatment of malignant or chronic pleural effusion due to the lower risk of complications during insertion and the increased patient comfort afforded by their small calibre[7]. However, small-bore tubes may present a greater failure rate than larger drains due to tube misplacement, dislodging, obstruction and kinking.

There are two main techniques for drain insertion: the Seldinger technique or the Verres need-

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le. Specifically, a new available type of drain, named UNICO (Redax, Mirandola Modena, Italy), employs a Verres needle with a blunt tip surface while passing through the chest wall, making the process potentially safer than the Seldinger technique. In fact, using the last procedure, the more traumatic Tuohy needle may cause damage to the chest wall, intercostal bundle, or lung parenchyma.

However, comparative studies regarding the outcomes of the two types of small-bore drainages are lacking in the literature, therefore it is not possible to assess if the two approaches provide comparable complications and failure rates because only single drain experiences have been reported[8,9].

In the present day, when particular attention is paid to available resources and it's critical to have information about true efficacy of various products in order to choose the one with the best cost-to-benefit ratio, a comparison of two drains in terms of efficacy and complications is essential.

Therefore, the aim of this study is to test the non-inferiority of the UNICO system compared to the Seldinger technique in small-bore chest drain insertion.

Patients and Methods

The study was designed as a prospective, non-inferiority, non-randomized observational analysis of patients who undergone small-bore drain insertion for pleural effusion of any aetiology at Fondazione Policlinico Gemelli IRCCS between February 2021 and September 2021.

All patients provided informed consent to participate in the study and to have their clinical data processed. The research was conducted according to the recommendations outlined in the Declaration of Helsinki.

This study was evaluated by the Institutional Review Board (IRB) of Catholic University of Sacred Heart and received IRB approval (ID 3312).

The clinical data of one hundred and seventeen patients was gathered in a prospective database.

For the purpose of the study, the two drains were compared as follows:

- Small-bore wire-guided drain (SBWGD) Smiths® [Portex Seldinger Chest Drainage Kit; (Smiths Medical, Minneapolis, MINN, USA)] 12 Fr chest drain (length 30 cm), requiring a Seldinger technique for its insertion. In detail, a metal wire is inserted in the Tuohy needle and then, after using a countersink, the drain is positioned and fixed using a 1 silk stitch.
- UNICO® Standard 12 Fr chest drain (length 22 cm). This is a single-step trocar with a Verres needle positioned in the trocar that is removed after the drain insertion. The drain is then fixed using a 1 silk stitch.

The type of drainage used was determined on a case-by-case basis by the operator, depending on their own clinical experience and considering the drainage availability at that moment. The drains were all connected to a Heimlich valve, and suction was applied only in case of incomplete expansion in absence of entrapped lung. All procedures were performed at the patient's bedside in the ward or the emergency room.

The anesthetic protocol consisted in the administration of local anesthesia (5 mg of lidocaine and 10 mg of ropivacaine prior to drainage insertion with a savage dose of 5 mg of lidocaine, if necessary), using a cutaneous puncture at the site of insertion.

The patients involved in the study met the following inclusion and exclusion criteria:

Inclusion criteria:
- Age > 18 years.
- Informed consent signed.
- Pleural effusion documented at chest X-ray or chest CR scan requiring chest drain insertion.
- 12 Fr drain insertion.
- Operator: Consultant or resident in thoracic surgery.

Exclusion criteria:
- Hemothorax.
- Anesthetic allergy.
- Empyema.
- Neurological disorders making the patient not collaborative or disoriented.

Patient sex, age, comorbidities, anticoagulant-antiplatelet therapy, hemoglobin, platelet count, INR, prothrombin time, body mass index, pleural effusion etiology, and presence of neoplasm were all considered in the collected clinical data.

Data regarding the kind of chest drainage, procedure duration, surgeon's expertise (consultant or resident), Visual Analogue Scale (VAS), the quantity drained, use of ultrasound, and presence of complications were also gathered during the procedure.

The major complications described and related to pleural drainage positioning are air leakage and

subcutaneous emphysema for lung perforation, diaphragm or a subdiaphragmatic organ perforation, hemothorax for puncture of large vessels or an intercostal vessel, pleural empyema, and hemopericardium due to cardiac injury.

Minor complications include infection of the surgical site, bleeding from the skin and pleural fluid leaking around the drainage tube.

Chest drainage failure was defined as the presence of one of the following conditions: mispositioning or displacement of the drainage that requires removal and replacement (for example, when the extremity of the drain ended the soft tissue of the thorax), the persistence of pleural effusion due to occlusion (despite washing out with physiological solution) or kinking of the drainage.

After chest drain insertion, patients were monitored throughout the duration of their hospital stay, during which clinical data was collected on the effusion progression and the chest drain removal.

All patients underwent a post-procedure chest X-ray during the first 24 hour, with subsequent controls based on clinical symptoms and the pleural effusion in those 24 h. Specifically in cases of massive pleural effusion, less than 1500 ml of fluid is drained on the day of the insertion to prevent re-expansion pulmonary oedema; instead, the drainage is kept open the next day to obtain a complete expansion of the lung.

The second evaluation of pain using a VAS scale was recorded on day 2.

The chest drain was removed in case of effusion volume being < 200 ml in the last 24 hour or if there was an indication to do palliative chemical pleurodesis in Video-Assisted Thoracic Surgery (VATS) or in case of chest drain failure.

For the aim of the study, two endpoints were considered:

- To compare the drainage failure among the two groups.
- To compare the complications rate among the two groups.

Surgical Intervention

Seldinger technique

The Seldinger technique involves the use of a pre-assembled kit that contains a 12 Fr pleural drain, a Tuohy needle, a dilator, a guide wire, a conical connector, and a three-way stopcock (Figure 1).

After identifying the catheter insertion site under ultrasound guidance, an incision is made with a scalpel blade at that point, previously locally anaesthetized. The metal guide wire is introduced through the Tuohy needle, which is used to slide the dilator through the chest wall. Once the dilator is retracted, the pleural drainage, *via* which pleural fluid drains out, is inserted.

Trocar technique

The Trocar technique by Unico Standard chest drain utilizes a preassembled percutaneous device

Figure 1. Seldinger chest drain 12 Fr.

Table I. Clinical and procedural characteristics of both groups.

Variables	117 Patients SBWGD (72)	Unico (45)	*p*-value
Gender (female)	57 (79.2%)	28 (62.2%)	0.045
Age	63.53 ± 14.82	64.87 ± 13.55	0.624
BMI		23.61 ± 5.31	24.07 ± 4.18
0.632			
Side (right)	48 (64.0%)	26 (57.8%)	0.238
Causes of effusions			
Neoplastic	51 (68.0%)	35 (77.8%)	0.216
Post-traumatic	3 (4.0%)		0 (0%)
Parapneumonic	4 (5.3%)		3 (6.7%)
others	14 (18.7%)	7 (15.5%)	
Hb (d/dl)	10.81 ± 2.02	11.09 ± 2.23	0.587
Platelets/ mcL	314,300 ± 191,880	332,160 ± 167,193	0.825
INR	1.11 ± 0.15	1.09 ± 0.14	0.568
Antiaggregant-anticoagulant therapy	26 (36.1%)	12	0.289
Operator			
Consultant	20 (27.8%)	12 (26.7%)	
Resident	52 (72.2%)	33 (73.3%)	0.896
Complications	1 (1.4%)	1 (2.2%)	1.00
Mean procedural time (min)	7.93 ± 3.02	7.09 ± 3.67	0.33

that contains a completely radiopaque polyurethane catheter with three holes and a distal opening for liquid drainage. Inside the catheter there is a mandrel with a Verres needle whose tip retracts during penetration and expands when the needle enters a free space (Figure 2). The unidirectional Heimlich valve is included into the percutaneous catheter, allowing fluid to be drained or washed without the requirement for a three-way stopcock and without the risk of air entering the pleural cavity (pneumothorax).

Statistical Analysis

Continuous variables were reported as mean ± standard deviation and compared using the student's *t*-test. Categorical variables were reported as numbers and percentages (%) and analyzed using Fisher's exact or the Chi-square test. Univariable and multivariable logistic regression analyses were applied to identify the predictors for drain dislodgement. Only variables with a *p*-value <0.2 at univariable analysis were considered for multivariable regression analysis.

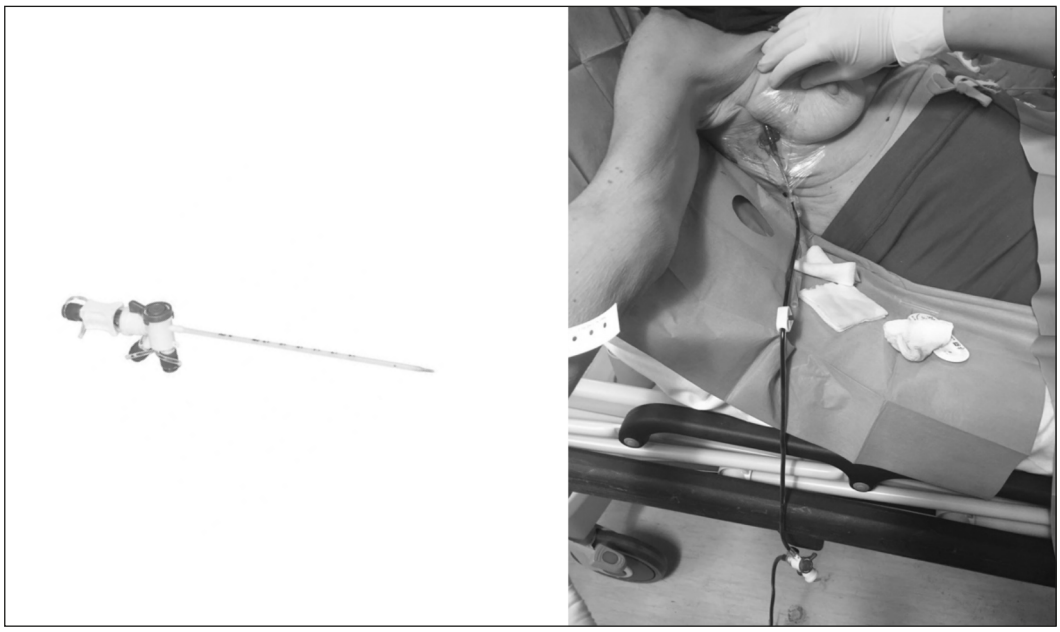

Figure 2. Trocar chests drain 12 Fr.

A *p*-value lower than 0.05 was considered statistically significant. The statistical analysis was performed using SPSS Statistics for IOS, Version 25.0 (IBM Corp., Armonk, NY, USA).

Results

During the study period, 117 patients met the inclusion criteria: 72 (61.5%) patients were enrolled in the SBWGD group and 45 (38.5%) in the UNICO group.

Clinical and procedural characteristics were reported in Table I.

In the majority of cases, pleural effusion was caused by tumor pleural implants (75.2%), and ovarian cancer was the most common tumor with pleural involvement (41.4%). In 39 patients (32.5%) there was a positive history of antiplatelet or anticoagulant therapy, and in 9 cases, the drainage was inserted while on acetylsalicylic acid or clopidogrel medication. However, oral anticoagulant therapy was always discontinued beforehand. Twenty-two patients receiving low molecular weight heparin had chest tube positioned within four hours from the last administration.

In 95 (81.2%) cases, the operator employed ultrasonography guidance, with the fifth intercostal space being the most common choice. The pleural effusion was of serous nature in 85.5% of cases.

In 32 cases (27.3%), the operator was a consultant thoracic surgeon, whereas in the remaining 85 cases (72.7%), the operator was a thoracic surgery resident.

There was no difference between the two groups in terms of clinical variables (BMI, age, side and causes of pleural effusion), blood coagulation parameters, antiplatelet and anticoagulant therapies, except for a higher number of females in group 1 (79.2% *vs.* 62.2%, *p*: 0.045), Table I.

The mean procedural time was 7.93± 3.02 minutes in group 1 *vs.* 7.09± 3.67 minutes in group 2, *p*: 0.35.

In the overall cohort, the median VAS during drain insertion was 2 (range 0-10), with 43 patients reporting no pain or =1, while only in 11 patients the VAS resulted higher than 5. Considering the two groups, the mean VAS at insertion was 2.22±1.47 (group 1) *vs.* 2.80±1.88 (group 2), *p*: 0.07.

The mean VAS at day 2 was 3.6±1.2 in SBWGD group *vs.* 2.7± 1.1 in Unico Group (*p*: 0.04).

There was no difference between the two groups in terms of complications (1 case of pleural fluid leakage around the drainage tube in both groups, *p*: 1.00), residual effusion (*p*: 0.84) and pneumothorax (*p*: 0.85) at the first post-procedural chest X-ray. During the study, 8 patients died of illness in the whole series.

At 2-days following the chest insertion, dislodgement was recorded in 3 patients (4.2%) in SBWGD *vs.*1 case (2.2%) in UNICO group (*p*: 0.231).

The four-day tube failure rate was 16.2% (19/117 patients), with 11.1% (8 patients) in the SBWGD group compared to 24,4% (11 patients) in the UNICO group (*p*: 0.063).

In further detail, the cause of drainage failure was blockage in 3 cases and dislodgement in 16 cases. Based on the type of tube, the blockage and dislodgement rates were 1.3% (1/72) and 8.3% (6/72) in the SBWGD group and 4.4% (2/45) and 22.2% (10/45) in the UNICO group, respectively.

The failure rate was 17.6% (15/85) when the operator was a resident and 9.3% (3/32) when the operator was a consultant, *p*: 0.239. In the UNICO group, the failure rate for consultants was 9% (1 case) compared to 31.2% (10 cases) for residents, *p*: 0.146.

The chest tube was removed (in 87.8% of patients in group 1 and 93.0% in group 2) after a mean period of 8.87±7.20 days after resolution of pleural effusion or tube dislodgement [7 cases in group 1 (12.1%) *vs.* 11 in group 2 (27.5%), *p*: 0.053].

Evaluating the main factors influencing drain dislodgement, only the type of drain was statistically significant at univariable analysis [Unico *vs.* SBWGD: HR (95% CI): 4.475 (1.209-16.653), *p*: 0.025]. At multivariable analysis, the factor showed only a trend toward significance (*p*: 0.06).

Univariable and multivariable analyses were reported in Table II.

Discussion

In this study, we compared two pleural drain techniques using two different small-bore chest drains for the initial treatment of pleural effusion, especially analyzing the safety profile and the failure incidence.

It is well known that larger-diameter tubes are extremely useful and indicated in the presence of blood or purulent effusion, while small-bore tubes are effective in case of serous one[10]. Particularly, Park et al[11] reported that a significant difference in effusion drainage was present only when the tube diameter was smaller than 8 Fr, suggesting that large bore and small-bore tubes with a diameter > 8 Fr are substantially equivalent for serous effusion resolution.

Table II. Univariable and multivariable analyses for factors influencing drain dislodgment.

	Univariate analysis		Multivariate analysis	
Variables	**HR [95% CI]**	***p*-value**	**HR [95% CI]**	***p*-value**
BMI	0.939 [0.818 - 1.078]	0.374		
Side	0.481 [0.107 - 2.165]	0.340		
Effusion type (neoplastic vs. others)	1.411 [0.310 - 0.6424]	0.656		
Operator (resident vs. consultant)	3.167 [0.514 - 19.492]	0.214	1.998 [0.518 - 7.7713]	0.315
Ultrasound guidance	0.895 [0.265- 3.027]	0.859		
Type of drain (Unico vs. SBWGD)	**4.475 [1.209 - 16.653]**	**0.025**	2.751 [0.956 - 7.919]	0.06

BMI: Body Mass Index; SBWGD: Small-Bore Wire-Guided Drain.

Based on this evidence and our clinical practice, in our operative unit we chose the type of tube according to the pleural effusion characteristics. Moreover, if the patient has no sign of empyema (fever, chest pain, white cells alteration, hydropneumothorax at the CT scan) or bleeding, and the effusion at the explorative puncture is serous, we always insert a small-bore drain.

However, we started our working experience using drainage only with the Seldinger technique, but the development of new materials, notably in the last decade, has increased the number of available drainages[7]. As a consequence, we recently have introduced the UNICO drainage system and are investigating if this type of chest tube presents comparable safety and efficacy features.

Often small-bore drainages carry a higher risk of blockage compared to large bore drains[12] with a higher incidence of kinking or misplacement. In our study, UNICO drainage had a greater dislodgement rate than Smiths drains, even if not statistically significant at multivariable analysis. It is interesting to note that after dislodgment, reinsertion of the chest tube was never required due to pleural effusion persisting in the thorax during that hospitalization. However, despite the higher dislodgment rate, in general, the UNICO system allowed complete drainage of the chest cavity; hence the goal of the drain insertion was achieved.

UNICO drainage derives from the thoracentesis kit, and unlike other types of tunneled drains, it was not designed for a long-term usage.

Moreover, the Unico available in the ward may have some limitations due to its length of 22 cm compared to the 30 cm of the SBWGD tube. In light of this and considering that in some situations the chest wall thickness may not be negligible, the adoption of the other model with a length of 40 cm ("UNICO Forty") may be appropriate for our patients.

Additionally, an interesting aspect is the increased rate of dislodgment rate according to the operator experience. In fact, if we focused on the operator in the UNICO group, 8.3% (1/12) of drain failures occurred when the operator was a consultant, compared to 30% (10/33) when the operator was a resident. Considering only this kind of drainage, the proportion of drainage failure for residents increases from 17.6% in the entire cohort to 30% in the UNICO group. This result is consistent with Davies et al[13] experience, who reported a greater displacement rate for operators with less experience. In detail, the authors reported a displacement rate of 30% among operators with less experience than consultants, underlining the importance of education and mentoring role played by experienced operators. In this study, the tubes were inserted by residents following adequate training and under the supervision of a consultant; yet, despite the efficiency in the tube insertion maneuvers, the resident's skills in tube fixation should not be underestimated.

On the other hand, it is interesting to note that the failure rate in our study is significantly lower compared to other previous retrospective analyses[13,14], which reported a chest drain failure of approximately 30 %. It is consistent with our group's prior experience, which reported a drainage failure rate of the 12.9% in a cohort of 1,092 patients[8]. The paper by Cafarotti et al[8], which demonstrates the large experience of our group in SBWGD, may explain the lower failure rate using this approach in comparison with the UNICO system, supporting the concept that if adequate training and experience are present, the failure rate may significantly decrease.

The two chest drains presented a similar result given that the pain evaluation during the insertion maneuvers was very low (of about 2 according to VAS scale) for both drains. It is an essential point considering the different insertion techniques,

since, especially with UNICO drains, a significant amount of strength must be applied to facilitate the insertion of Verres needle. However, we believe that a substantial portion of this outcome may be explainable by the local anesthetic protocol used, which consisted of administering lidocaine and ropivacaine and then wait for the patient's response to determine the anesthetic efficacy. Our results are in line with Cafarotti et al[8], who reported excellent pain management (mean VAS 4.6) using small-bore chest tubes. At the VAS pain assessment two days after insertion, UNICO drain seems significantly better tolerated than SBWGD drain ($p<0.04$), perhaps because polyurethane is softer and more comfortable than PVC.

Furthermore, we evaluated the safety profile of both drains, and we had encouraging results; the complication rate was very low, with only 2 cases equally distributed among the two groups. Moreover, the two drains demonstrated an excellent safety profile also in the case of antiplatelet-anticoagulant treatment. Indeed, in our series, the procedure was performed independently from the administration of acetylsalicylic acid, clopidogrel and within 4 hours of the administration of low molecular weight heparin. This approach was adopted since the antiplatelet agent assumption requires two more days of suspension before chest drain insertion, while in the case of new oral anticoagulant (NOAC) therapy, the insertion was delayed only by 24-48 hours, if possible.

Finally, in case of K vitamin antagonist, the oral intake was discontinued, and then the drain was inserted with an International Normalized Ratio less than 2. These results are in line with other studies[8,13] that reported a very low rate of bleeding following chest drain insertion. However, in these studies it is not specified if patients received any kind of antiplatelet-anticoagulant medication. To the best of our knowledge, this is the first report describing the safety profile associated with administration of antiplatelet-anticoagulant drugs. Despite the need for a larger cohort to validate these findings, this study may be considered as an indication for small-bore tube insertion in patients undergoing antiplatelet-anticoagulant therapy, suggesting that the insertion is safe even during acetylsalicylic acid and clopidogrel intake.

In this study, we also did not experience complications that needed invasive treatments, such as wire removal in thoracoscopy following its dislodgement in the pleural cavity[8]. This is unusual but possible complication using SBWGD, with practically two cases reported in the literature, even if in one case, the wire was removed bedside under ultrasonography guidance[15]. In contrast, one of the UNICO benefits might be the absence of wire, eliminating this risk and providing a potential advantage for this type of drain.

In terms of costs, small-caliber drainage kits have a higher cost. However, it should be noted that in most centers, large-caliber drains require a surgical procedure that is performed in the operating room and sometimes with assistance of an anesthesiologist for sedation, while small-caliber drains are inserted at patient's bedside or in the emergency room.

In this study, we observed a very low rate of complications, with no major and two minor complications in the entire group. This is probably due to our long-term expertise with this type of small drainages and with the large number of procedures performed in our hospital each year (more than 400 in a year).

To our knowledge, few studies[8,16,17] have compared the outcomes of two drainage placement techniques: one work published in 2016[16] involved 124 patients who underwent a Trocar procedure or the Seldinger technique. Drains ranging from 8 to 12 Fr were used in this study for massive transudative effusions, parapneumonic effusions and empyema. In some cases, the procedure was repeated, particularly in patients with neoplastic effusion. A total of 193 procedures were performed with the Trocar technique and 38 with the Seldinger technique. The study was conducted retrospectively, and the findings revealed that the Trocar technique is faster and easier, but the Seldinger technique is a viable option that can be used when the former fails.

Further, assuming this is a non-randomized trial, the study we present is the only prospective study that compares two drains of the same caliber using two different techniques.

Considering that only malignant pleural effusions account for more than 150,000 new cases annually in the US and around 100,000 cases in Europe[18], its management requires a large number of different specialists including pneumologists, thoracic surgeons, emergency doctors, and anesthesiologists.

Undoubtedly, the fact that both techniques described are simple with a low complication rate, as well as their similarity to thoracentesis, makes the procedure appealing to many professional medical figures. The social and economic implications of this health problem and its treatment have a profound impact on the medical community.

Limitations

There are some limitations to this study. For the kind of patients that sometimes require an urgent positioning of a drain, the study was designed as non-randomized and solely included the prospective data collection. Since all the procedures were performed at the patient's bedside, the kind of drain available at the moment of procedure had to be considered. In our hospital, each ward or emergency unit can have only one type of drain available at the time of procedure. As a result, the operator used one of the two types of drain on the basis of drainage availability in that setting at that time and according to the urgency of the case. Second, while this is a relatively small study, the sample size was estimated to achieve statistical significance in a non-inferiority trial, as well as to assess the main endpoint: the safety and reliability of the two techniques using two different drain systems. To the best of our knowledge, this is the first study in the literature comparing two kinds of small-bore drains, showing that both systems are effective in pleural effusion treatment. Finally, there was a difference in operator expertise in the two-drain management and insertion. The Seldinger drains had been used for over 20 years, while the UNICO system was introduced to our hospital only a few months before the study began. However, in our hospital, over 400 small-bore drains are inserted in a single year, and all the operators have been trained in the UNICO system management. Thus, despite the possibility of bias, several precautions were adopted to minimize them.

Conclusions

In this non-inferiority, prospective study, we compared two different chest drains insertion technique based on Seldinger or Verres needle technique (UNICO) for the initial treatment of pleural effusion. In terms of safety and drainage of pleural effusion, the performance of both drains was similarly excellent. At 5 days after insertion, the UNICO drain had a slightly higher failure rate compared to Seldinger drains, even if not statistically significant, and apparently this was attributed to less expertise of the operator. For this reason, when there is suspicion of malignant effusion requiring long-term drainage, we recommend longer drainage. However, following a dislodgment, the re-insertion of the tube was not necessary, meaning that the resolution of the effusion was achieved.

Further large, randomized studies are needed to validate these data.

Conflict of Interest

The Authors declare that they have no conflict of interests.

Authors' Contributions

Conceptualization, M.T. Congedo, M. Chiappetta, D. Nachira; methodology, D. Nachira; validation, F. Lococo, V. Porziella, M.L. Vita, L. Petracca-Ciavarella; formal analysis, D. Nachira; data curation, G. Calabrese, D. Tabacco, A. Nocera, M. Chiappetta and C. Sassorossi; writing – original draft preparation M.T. Congedo and M. Chiappetta writing – review and editing, M. Chiappetta, D. Nachira and K. Kuzmych; supervision, S. Margaritora and E. Meacci All authors have read and agreed to the published version of the manuscript.

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Availability of Data and Materials

The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request.

Ethics Approval

The study was conducted in accordance with the Declaration of Helsinki. This study has been approved by the Institutional Review Board of Catholic University of Sacred Heart and received IRB approval ID 3312.

Informed Consent

Informed consent was obtained from all individual participants included in the study.

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