

Thoracic vent versus conventional intercostal tube drainage in management of pneumothorax in a tertiary referral centre

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ABSTRACT

Introduction: Strategies in managing primary spontaneous pneumothoraces are shifting toward simple aspiration and ambulatory follow-up rather than the traditional chest tube and hospital admission. This study is to determine the differences in outcome between the treatment of pneumothorax using a Thoracic Vent (TV) versus conventional intercostal chest tube drainage (CITD) in terms of pain (Visual Analogue Score, 0-10 cm), complications, rate of expansion, and length of stay (LOS).

Materials and Methods: Randomized single-center prospective interventional study of inpatient pneumothorax patients. Subjects were randomized to treatment with True-Close Thoracic Vent with Heimlich valve or conventional chest tube. Both arms received standard medical care and analgesia. Pain score was assessed at baseline (2 hours post insertion), 24 hours after, and before removal.

Results: Twenty subjects were recruited and randomly assigned to treatment with TV (n=10) and CITD (n=10). The mean pain score at baseline (2 hours post insertion) for TV was 1.36. The mean time to chest expansion in those treated with TV is 1.9±0.56 days and 4.9±2.23 days for the CITD group. The mean time of removal in TV was about 3 days, while CITD was almost 8 days. Mean LOS in those treated with TV and CITD was 4.8±3.6 days and 13.1±4.7 days, respectively. We recorded 3 cases of recurrences within 14 days from both groups.

Conclusion: Pain scores were significantly lower in the TV group, and the lung expansion and LOS rate were substantially shorter than CITD. There were fewer complications in the TV group, and no difference in pneumothorax recurrence on follow-up between the two groups.

KEYWORDS:

Pneumothorax, Thoracic Vent, Tru-close

INTRODUCTION

Pneumothorax means air in the pleural cavity (i.e., interspersed between the lung and the chest wall). Back then,

most pneumothorax was secondary to tuberculosis, although some were recognised as occurring in otherwise healthy patients ('pneumothorax simple').¹ This classification has persisted since then, with the first modern description of pneumothorax occurring in healthy people (primary spontaneous pneumothorax, PSP) as was defined by Kjærgaard in 1932.¹

Secondary pneumothorax (SSP) is associated with underlying lung disease, distinguishing it from PSP. The sequelae of pneumothorax in patients with pre-existing lung disease are higher, making it more challenging. Both PSP and SSP are considered spontaneous pneumothorax. Another known cause of pneumothorax is non-spontaneous or iatrogenic pneumothorax. As the name implies, it is caused by trauma and procedure-related, i.e., most commonly from subclavian vein catheterisation and transthoracic biopsies.²

Treatment of pneumothorax aims to eliminate intrapleural air and re-expand the collapsed lung simultaneously, while the long-term goal is to prevent a recurrence. To achieve these, various non-operative initial treatments have been used in the clinical setting: from the non-invasive method of observation with/without supplemental oxygen to invasive procedures such as intercostal chest catheter (ICC), e.g. Seldinger chest drain, pleural catheter, pigtail catheter, or conventional intercostal tube drainage (CITD). They can be connected to a suction system, an underwater closed system, or a one-way valve suction system (Heimlich valve).³

Pneumothorax management is shrouded in controversy despite being a known disease. Evidently, attempts at standardizing its management have been made by guidelines published by the American College of Chest Physicians (ACCP) in 2001, the Belgian Society of Pulmonology in 2005, and the British Thoracic Society (BTS) in 2023.^{4,6}

Treatment for PSP can be personalized according to patient preference, symptoms, and the size of the pneumothorax. There is an option for a conservative method (non-intervention) in selected patients and treatment with simple aspiration or small-bore ICC.^{4,6}

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However, in secondary pneumothorax, ACCP recommends ICC for pneumothorax size >3 cm (apex to cupola) while the latest BTS guideline states that pneumothorax size no longer dictates the need for invasive management, but still informs procedural safety, with chest drain use now driven mainly by high-risk clinical features.^{4,6} The Belgian Society of Pulmonology guidelines recommend a small-bore ICC connected to a Heimlich valve.⁵

According to a systematic review by Brims et al., using the Heimlich valve can improve patients' comfort and mobility and prevent hospital admission with a comparable outcome to current practice.⁷ The rate of complications with the Heimlich valve was reported to be <1%.⁷

Alternatively, the Thoracic Vent (TV) is another tool allowing ambulatory pneumothorax treatment. A study in Korea, in which TV was inserted under fluoroscopic guidance for the treatment of pneumothorax, achieved a 100% success rate without complications (18/18 patients). They have concluded that TV is a safe and effective method for immediately treating pneumothorax. As this was a 3-year prospective study, they also reported a high recurrence-free overall success rate (72.2%, 13/18 patients).⁸

Thus, in summary, TV is a relatively new device for treating primary, secondary, and iatrogenic pneumothorax and has the potential to change the paradigm of inpatient management of pneumothorax and open the horizon of outpatient care for pneumothorax. This is a new concept, especially in the Malaysian scenario, as the mainstay of treatment is inpatient CITD, and the plausibility of outpatient care has yet to be explored. The rationale for this study was to compare the TV with the CITD, as large-bore drainage remains the standard practice for pneumothorax management in our centre. Small-bore ICCs would have introduced variability; hence, they were not selected for this pilot comparison. TV was chosen as it not only represents a small-bore device but also offers the advantage of facilitating early ambulation, with the potential for future use in outpatient management within our local healthcare setting. Hence, we aim to determine the differences in outcome between the treatment of pneumothorax using a TV versus CITD. Our primary objective was to determine differences in outcome between TV and CITD regarding pain, complication rate, rate of lung expansion, and length of stay (LOS). Our secondary objective was to assess the recurrence of pneumothorax 10-14 days after discharge.

MATERIALS AND METHODS

Study design

A randomized single-center prospective interventional study of pneumothorax patients in the National University of Malaysia was conducted between December 2020 and March 2024. The study was approved by the Research Ethics Committee, National University of Malaysia, FF-2021-016. The sample size was based on Julious' calculation method; for a pilot study, the recommendation is a sample size of 12 per group. Considering the 10% dropout rate, 14 per group was obtained.⁹

Patients diagnosed with pneumothorax were recruited prospectively from the emergency department (ED), general wards, and Interventional Radiology (IR) department. We included the following patients: those older than 18 years, those with spontaneous primary pneumothorax, or secondary pneumothorax with a size of more than 20%, based on Collin's method.¹⁰

Collin's method of calculation of pneumothorax size (%) = $4.2 + (4.7 \times [A + B + C])$ in cm, where A is the maximal apical interpleural distance, B is the midpoint of the upper half of the collapsed lung. C is the midpoint of the bottom half of the collapsed lung.¹⁰

Subjects were excluded if they had bilateral pneumothorax, tension pneumothorax, or hydropneumothorax. Subjects who are ventilated, pregnant, have a body mass index (BMI) of more than 35 kg/m², thrombocytopenia (platelets < 50,000 x 10⁹/L), and coagulopathy, INR >1.5, were also excluded from this study. Following enrolment, baseline demographic data, including age, gender, race, BMI, smoking history, and comorbidities, were recorded.

Procedure

Eligible subjects who consented to the study were then randomized using block randomization. They are randomized with a block of 4 with random permutations of 2 groups: group A, Thoracic Vent (TV), and group B, conventional intercostal tube drainage (CITD).

A TV size 13 Fr with a length of 10 cm was used in this study for subjects recruited in this group. Based on imaging, it was inserted either in the second intercostal space in the midclavicular line or in the most suitable location. The procedure was done by a trained doctor (a registrar or respiratory fellows with supervised training in pleural procedures) or an interventional radiologist, under standard local anesthesia with lignocaine 2%.

A red signal diaphragm indicates when the trocar has initially entered the pleural space during insertion and reflects pressure changes in the pleural space. The movement of the red signal diaphragm during breathing will indicate drainage of a pneumothorax (Figure 1A). This movement will eventually stop once the lung is fully expanded. A specialized plug (provided in the TV insertion kit) was used to occlude the TV to confirm the resolution of the pneumothorax. A repeat chest radiograph following 4 hours of occlusion that showed no recurrence of pneumothorax will confirm no air leaks. The TV can then be safely removed after confirmation that any air leaks have resolved by evidence of the absence of movement of the signal diaphragm, and the patient remains asymptomatic.^{8,11} Figure 1B shows the image of the thoracic vent and how it looks on a chest radiograph (Figure 1C). Figure 1D shows a double-valve aspiration cannula connected to a self-sealing port, which attaches to a syringe to allow manual air aspiration from the pleural cavity.

For those who underwent CITD management, a chest tube, size 24 Fr, was inserted through the fifth intercostal space in the safety triangle under local anaesthesia (lignocaine 2%) and connected to closed underwater seal drainage. Daily

Table I: Baseline characteristics and outcome of pneumothorax patients

Demographics	Pneumothorax patient		p-value
	TV (n=10)	CITD (n=10)	
Age (in years)			
Mean	49.8±19	56.20±22	0.496a
Sex, n (%)			
Male	8(80)	9(90)	0.53b
Female	2(20)	1(10)	
Ethnicity, n (%)			
Malay	7(70)	8(80)	0.61b
Chinese	3(30)	2(20)	
Indian	0	0	
Others	0	0	
Smoking status, n (%)			
Non-smoker	3(30)	5(50)	0.361b
Active smoker	7(70)	5(50)	
BMI (kg/m ²)			
Mean	20.8±2.7	22.4±5.5	0.43a
Co-morbidities n			
Diabetes Mellitus	1	3	0.264b
Hypertension	1	4	0.120b
Ischemic Heart Disease	0	1	0.310b
Chronic Obstructive Pulmonary Disease	2	0	0.136b
Dyslipidemia	2	0	1.00b
Lung Cancer	2	2	1.00b
Retroviral Disease	1	1	
Types of pneumothoraces:			
Spontaneous primary	1	3	n/a
Spontaneous secondary	7	6	
Iatrogenic	2	1	
Lung involvement n,:			
Right	4	8	n/a
Left	6	2	
Size of Pneumothorax			
Mean	59.5% ±24.9	62.4% ±23.0	0.788b

The data are described using mean + SD or n (%)

a Paired t-test;

b Pearson Chi-square;

p-value < 0.05 is significant

n/a -not applicable

Table II: Comparison of Pain score within TV and CITD groups (n=20) difference

Variables	TV (n= 10)			CITD (n=10)		
	Baseline Mean (SD)	Prior to removal Mean (SD)	p-value	Baseline Mean (SD)	Prior to removal Mean (SD)	p-value
Sleeping	1.3±0.51	1.2 ±0.42	0.591 ^a	3.0±0.67	2.9±0.99	0.509 ^a
Shower	1.3 ±0.51	1.1±0.32	0.343 ^a	3.0±0.67	3.0±0.82	1.00 ^a
Toilet	1.4 ±0.52	1.1±0.32	0.193 ^a	3.1±0.74	2.9±0.74	0.343 ^a
Deep Breathing	1.5±0.52	1.1±0.32	0.104 ^a	3.0±0.67	3.1±0.88	0.726 ^a
Ambulation	1.3±0.53	1.1±0.32	0.343 ^a	3.2±0.62	2.9±0.74	0.279 ^a

^a Paired T-test; p-value < 0.05 is significant

Table III: Pain reduction during daily life activities and pain change from before removal compared to baseline (2 hours post insertion) between TV and CITD

Variables	TV	CITD	p-value
Sleeping	-0.1(+0.57)	-0.2(+0.92)	0.773a
Shower	-0.2(+0.63)	0(+0.94)	0.580a
Toilet	-0.3(+0.68)	-0.3(+0.95)	1.00a
Deep breathing	-0.4(+0.69)	0.1(+0.88)	0.175a
Ambulation	-0.2(+0.20)	-0.3(+0.26)	0.764a
Pain change from prior to removal compared to baseline, n(%)			
Reduction /no change in pain	9 (90%)	8 (80%)	0.531
Increase pain	1 (10%)	2 (20%)	

The data are described using mean + SD.

^aIndependent t-test; p value <0 .05 is significant

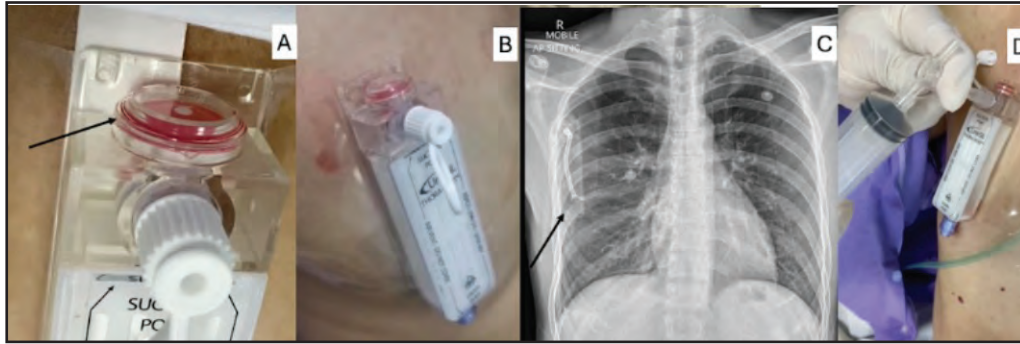


Fig. 1: The red signal diaphragm (A) on the thoravent. Image of the thoracic vent (B) on the chest wall and a chest radiograph (C). The double-valve aspiration cannula is connected to a self-sealing port, which attaches to a syringe to allow manual air aspiration from the pleural cavity. (D)

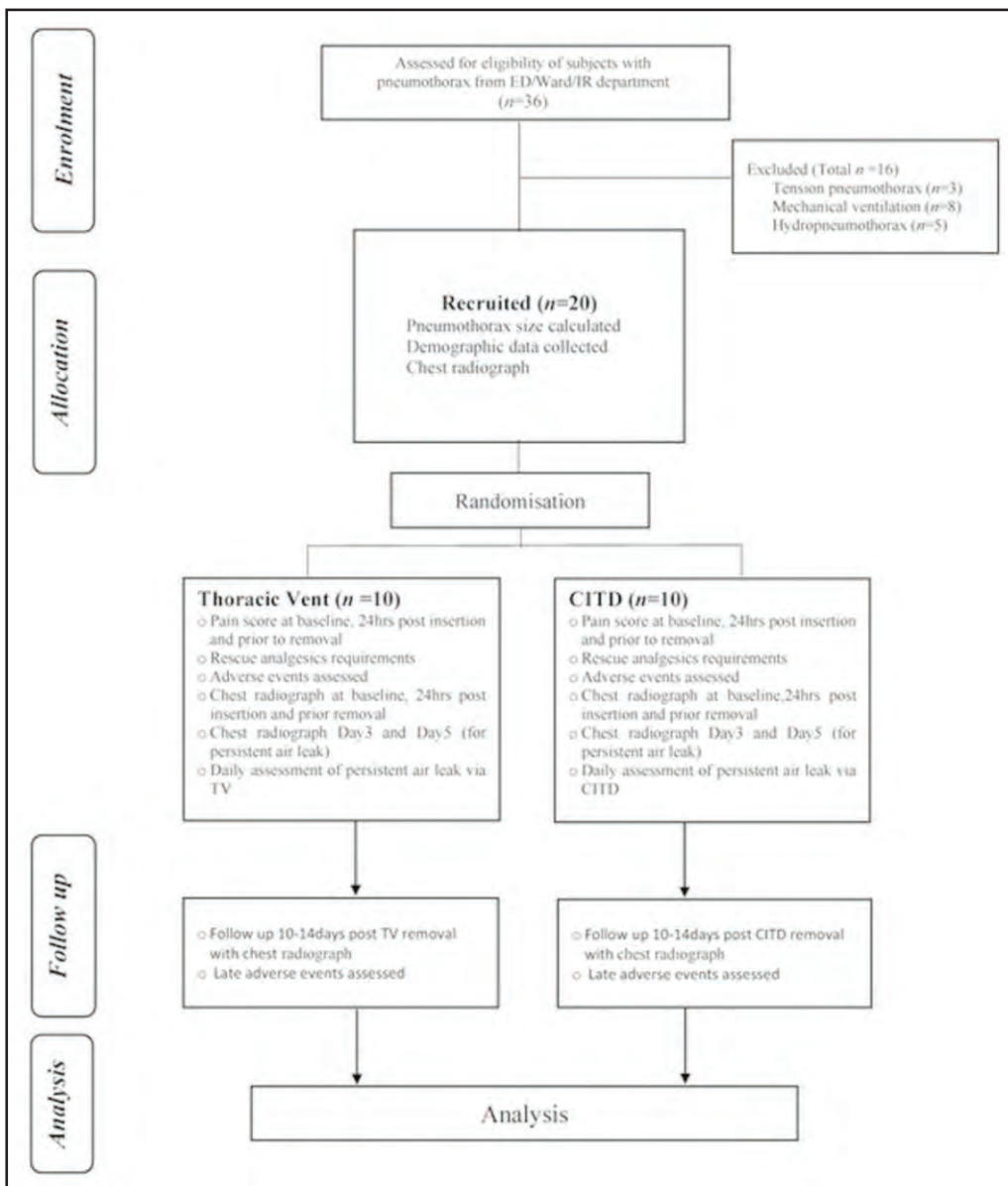


Fig. 1: Consort flow chart

assessment of the CITD was done to ensure the system is intact, such as inspection of fluid oscillation with respiration within the tube. We also ensured the tube was not accidentally clamped and flushed with saline when necessary.

Pain score was assessed at three intervals: at baseline (2 hours post insertion of TV/CITD), 24 hours post insertion, and 1-2 hours before removal.

Two hours following insertion of either TV / CITD, a baseline pain score was recorded to allow the local anesthetic to subside and before prescribing systemic analgesics. Pain scores were recorded upon interviews at the given intervals for different activity levels of daily life (i.e., sleep, showering, deep breathing, going to the toilet, ambulation), depending on the patient's ability, according to the Visual Analogue Scale (VAS) for pain (0-10cm). The pain score assessment during various activities was adapted from a study by Kim et al.⁸

Standard analgesics were given to both arms: oral tramadol 50 mg 8 hourly post-procedure, with intravenous morphine permitted as rescue analgesia in accordance with the TIME 1.¹² While paracetamol and NSAIDs can be considered as adjuncts, they were not adopted in this study as we aimed for a standardized analgesic protocol across both groups.

Subjects were then followed up daily till discharge/removal of TV/CITD to assess persistent air leak. Serial chest radiographs were also done, similar to the assessment of pain scores, i.e., at 2 hours post insertion, after 24 hours, and before removal, to assess for chest expansion. Repeated chest radiographs were done on days 3 and 5 for those with persistent air leaks. Patients in the TV group with persistent air leaks on day 3 and significant pneumothorax were converted to CITD. On Day 5, a referral to cardiothoracic surgery was made for those with persistent air leaks.

Follow-up was done 10-14 days post removal of TV/CITD to assess symptoms, and a chest radiograph was repeated to determine recurrence of pneumothorax.

Technical success was defined as successful placement of the TV/CITD within the pleural cavity without procedure-related complications. After TV/CITD insertion, clinical success was described as a complete resolution of baseline clinical symptoms and/or pneumothorax-related signs.

Statistical analysis

All data were analyzed using Statistical Package for Social Sciences (SPSS) version 27 according to 'intention to treat' analysis. The continuous variables were tested with the Student t-test for normal distribution and the Mann-Whitney U test for non-normal distribution to compare the TV and the CITD group. The categorical data were tested using the Pearson Chi-square and Fisher's exact tests. The data results between the two groups were analyzed using an independent-sample t-test or its equivalent non-parametric Mann-Whitney U test for parameter non-normal distribution. Paired t-tests were used to analyze data in each group. Statistical significance was declared when $p < 0.05$.

RESULTS

A total of 36 patients were screened. Twenty patients fulfilled the inclusion criteria and were successfully recruited for this pilot study: the study design and CONSORT flow diagram are shown in Figure 2.

Patients' baseline characteristics and outcomes are summarized in Table I. The mean age, in years (+ SD), for the TV arm and CITD was $49.8 \pm (19)$ and $56.2 \pm (22)$, respectively. In both arms, males were predominant, with 80% in TV and 90% in CITD. There were 70% of active smokers in patients treated with TV, while those treated with CITD were only half. Most (70%) of the pneumothoraces treated with TV were secondary and involved the left lung. In comparison, those treated with CITD were mainly engaged in the right lung. The size of pneumothoraces was similar in both arms: TV ($59.5\% \pm 24.9$) and CITD ($62.5\% \pm 23$).

TV had an 80 percent clinical success while those in the CITD arm had a 70 percent clinical success rate. Three patients (30%) were referred for surgical intervention as inpatients. An Interventional Radiologist inserted sixty percent of the cases treated with TV. There was one conversion to chest tube from TV due to a ruptured bulla due to vigorous coughing after complete resolution of pneumothorax at day 3, which then resolved with CITD. One referral to cardiothoracic was done under the TV arm due to failure to achieve clinical success. Patient underwent video-assisted thoracoscopy, which converted to open thoracotomy for bullectomy and adhesiolysis. This patient was followed up according to the intention-to-treat analysis in the TV arm to which he was initially assigned.

Both TV and CITD had one patient who developed subcutaneous emphysema as a procedure-related complication. We recorded 2 cases of dislodged chest tubes and 1 case of procedure-related infection in the CITD arm.

The mean time to chest expansion in those treated with TV is 1.9 ± 0.56 days, while the mean time to chest expansion in those treated with CITD was 4.9 ± 2.23 days. The mean time of removal in TV was 3.2 ± 2.93 days, while CITD was 7.8 ± 3.91 days. Mean LOS in those treated with TV was 4.8 ± 3.6 days, and in those treated with CITD was 13.1 ± 4.7 days.

Ten to 14 days after removal of TV/CITD, there was one recurrence of pneumothorax in the TV arm and 2 in the CITD arm. The mean pain score at baseline (2 hours post insertion) in TV.

Mean pain scores at different activity levels and mean reduction of pain scores are shown in Tables II and III, respectively. Ninety percent of cases treated with TV had a decrease in mean pain score from before removal compared to baseline, while CITD noted a sum of 80 percent as per Table III.

DISCUSSION

There has been a paradigm shift in the strategies for managing primary spontaneous pneumothoraces from the traditional chest tube and hospital admissions to simple aspiration and ambulatory follow-up.⁷ Some hospitals in Japan have been treating pneumothorax using a minimally

invasive strategy via the thoracic vent. It was deemed advantageous for patients as they are not required to be admitted.^{11,13,14} A previous study showed a reduction in the percentage of hospitalized patients in those with simple aspirations compared to those with intercostal tube drainage.¹⁵

A TV is a 13 Fr thoracic tube containing a one-way valve with a small extracorporeal box (9×2.5×2 cm). It is beneficial for draining air but not fluids because the capacity of the extracorporeal box is only 30 mL. Therefore, a TV is not indicated for a pneumothorax with a significant pleural effusion. In a study by Martin et al., a TV is indicated for spontaneous and iatrogenic pneumothoraces without pleural effusion.¹⁶

As with many medical devices, there is always some degree of pain related to the insertion of the device. TV is not excluded from this known fact. However, few studies assess the pain associated with the insertion of TV; hence, not much data is available. A Korean pilot intended to evaluate TV's technical feasibility and procedural safety in the outpatient management of pneumothorax also included the mean pain score in daily activities while the patient is on TV.⁸

Fysh et al. have highlighted that small-bore catheters are generally associated with less pain than large-bore tubes, with comparable efficacy, although robust randomized data remain limited.¹⁷ Our findings support this observation, as patients in the TV group (small bore) reported significantly lower pain scores than those managed with CIRD.

In our study, the mean baseline pain score at rest after insertion of TV is 1.36(0.5), while in the CIRD group, it was 3.06(0.6). This result corresponds to the mean pain score from the Korean pilot trial, with a mean of 2.4.⁸

In our study, even though patients in the TV arm have less pain score reduction during various activities, as in Table III, there is no statistical difference compared to patients in the CIRD arm. This could be explained by the fact that patients in the TV arm already had a lower baseline pain score than those in the CIRD arm, as shown in Table II.

However, pain is often regarded as a scaled variable when it is not. Using the mean pain score (VAS, cm) alone may not be accurate, as subjects have different baseline pain scores. In our trial, we have included the degree of mean pain reduction, from before removal of TV/CIRD to baseline pain score, as stated in Table IV. Most (90%) of patients in the TV group and 80% of CIRD patients had a reduction of pain scores of at least 2 points (Table IV).

The minimal clinically important difference (MCID) for pain on the VAS has been reported to range between 8–40 mm (0.8–4.0 cm) on a 100 mm scale in acute pain studies, depending on baseline severity and methodology.¹⁸ Tashjian et al. specifically reported an MCID of approximately 1.4 cm in VAS for pain in surgical patients.¹⁹ Based on these data, we considered a ≥ 1.0–1.5 cm reduction on the 10 cm VAS to represent a clinically meaningful difference in our study population.

Pain is not the only factor that should be considered. Patients' preference, especially in elderly patients, where the pain threshold might be higher, but the ability to be mobilized would have a better impact on avoiding complications like orthostatic pneumonia from prolonged immobilization. Hence, TV would have a better advantage over CIRD in this aspect.

With regards to complication, in a systemic review by Brims et al. in 2013 on ambulatory treatment in the management of pneumothorax, they have managed to identify from the total reported cases (n= 1235) there were four hemothorax, one local cellulitis, two blocked tubes due to exudate, eight dislodged catheters, four subcutaneous emphysema and one tension pneumothorax due to incorrect connection.⁷ In our study, 10 percent of the TV patients had subcutaneous emphysema. While in the CIRD arm, there were noticeably more complications, such as two dislodged catheters, one tube-related infection, and one subcutaneous emphysema. This could be due to several factors: TV allows earlier tube removal. This, in turn, reduces the time the tube dwells in the pleural cavity and lessens the chance of causing infection. Our findings were similar to the Danish study that showed more drainage-related complications in patients treated with CIRD than TV.²⁰

The mean time for chest expansion for TV was 1.9(0.56) days and 4.9(2.23) days for the CIRD. We postulate that the delay in lung expansion observed in the CIRD group compared to the TV group may be due to the larger bore tube causing greater pleural irritation and patient discomfort, which limited early mobilization and contributed to slower expansion.

Meanwhile, the mean time for removal for TV was 3.2 days (2.93), and for CIRD, it was 7.8(3.91). This corresponds to the results in the Danish retrospective trial, which showed a mean of 4.9 days in the small-bore/TV, and CIRD had a mean of 8.3 days. We showed 80 percent clinical success in patients treated with TV, with an 80 percent technical success. CIRD showed 70 percent clinical success and about 40 percent technical success. Martin et al. studied thoracic vent mainly in iatrogenic pneumothorax, which showed a similar drainage time of 3.3 days and a success rate of 85%.¹⁶ Samelson and Anbalayanan et al. studied thoracic vent in primary spontaneous pneumothoraces and showed similar drainage time, which was 5.5 days and 3.2 days, with a success rate of 82.4% and 100%, respectively.²¹⁻²²

Patients' stay in the TV group was 4.8 days (3.6), while the CIRD was 13.1 (4.7) days. Comparing these results with the retrospective trial in Denmark, they recorded a mean length of stay of 6.9 days (TV and Portex/pigtail chest tube), while the large-bore chest tube was 11.8 days.¹⁹ Outpatient management of pneumothorax using TV has been successful in the Korean pilot study and Japan.^{8,11,13,14} Massongo et al. found that hospital-stay costs can be reduced by applying simple aspiration as the first step in an outpatient management algorithm. Furthermore, if the simple aspiration fails, a portable small-bore chest tube connected to a Heimlich valve is inserted, and the patient is sent back home.²³

This could offer a safe first step in the outpatient management of pneumothorax. Furthermore, this would support the findings of TV to reduce medical expenses as it reduces hospital stay and has been proven efficacious as an outpatient management.¹¹ This, in turn, is associated with significant economic benefits.¹¹

Our study differs from the Korean pilot trial in both setting and design.⁸ The Korean study evaluated 18 patients with spontaneous and iatrogenic pneumothoraces managed with Thoracic Vent under fluoroscopic guidance in an outpatient setting, reporting high technical success and a recurrence-free rate of 72.2% over three years.⁸ In contrast, our randomized pilot study involved 20 inpatients. It directly compared Thoracic Vent with conventional large-bore intercostal tube drainage, demonstrating lower pain scores, faster lung expansion, and shorter hospital stay in the TV group.

These differences underscore the relevance of our study in highlighting TV as a viable alternative to large-bore drainage within the local inpatient context, while also paving the way for future outpatient applications. Both studies support the broader role of TV across different clinical settings.

Our study possesses some limitations. This trial was a prospective pilot study done in Malaysia with a few participants, partly due to the COVID-19 pandemic, as our institution was a centre for managing COVID-19 patients. Future multi-centre randomized controlled trials with longer study durations are required to assess the effect of TV further compared to CITD. They may also compare non-intervention, minimal intervention/ambulatory management, and conventional ICD regarding hospital stay, pain score, recurrence rates, and cost-benefit analysis.

We concluded that pain associated with TV was significantly less compared to CITD and had fewer procedure-related complications. We also noted that expansion and hospital stay rates were shorter in TV than in CITD. Our findings support the idea that TV can be used to manage pneumothorax outpatients.

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