Early View

Original Research Article

The Role of Clamping Before Removal of a Chest Tube in Post-Surgical and Pneumothorax Patients Using Digital Drainage Systems: A Non-inferiority Randomized Trial

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The Role of Clamping Before Removal of a Chest Tube in Post-Surgical and Pneumothorax Patients Using Digital Drainage Systems: A Non-inferiority Randomized Trial

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The listed authors declare that there is no conflict of interest.

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Author contributions

WSB and JAS designed the study in consultation with MAE. The study was performed by WSB, RNH, QSDM. MAE helped with the interpretation of the statistics. WSB wrote the manuscript supervised by MLD, DJS, JAS. All authors approved the final manuscript.

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Abstract

Introduction:

Digital drainage devices have revolutionized chest tube management by providing continuous and objective measurements of air leaks. However, clamping trials remain common practice, influenced by expert opinion, concerns about recurrent pneumothorax, and a lack of prospective evidence. This study evaluates whether chest tube removal based solely on digital drainage data is as effective and safe as traditional clamping trials in patients with post-lung surgery or pneumothorax.

Methods:

In this single-center, open-label, non-inferiority study, 92 adult patients were randomized to either a no-clamping group (intervention) or a clamping trial group (control). The primary outcome was chest tube reinsertion within 24 hours due to recurrent ipsilateral pneumothorax.

Results:

92 patients were randomized, of whom 83 were included in the per-protocol analysis. The majority of cases were post-operative after pulmonary resection surgery. Chest tube reinsertion within 24 hours occurred in 0 of 44 Clamping Group patients (0.0%) and in 1 of 39 No-Clamping Group patients (2.6%) (risk difference, 2.6 percentage points; 95% CI, –2.4 to 7.5), meeting the non-inferiority margin. In 6 (13.6%) Clamping Group patients, clamping led to progressive pneumothorax, requiring resumed drainage. Secondary outcomes: total pneumothorax incidence within 24 hours and 30 days, chest tube duration, and hospital stay were comparable.

Conclusion:

This study shows that chest tube removal guided solely by digital drainage systems, is not inferior to the traditional clamping method in preventing recurrent pneumothorax, supporting the safety of this approach. In a notable proportion of patients, clamping resulted in progression of pneumothorax and prolongation of drainage.

Keywords:

Pneumothorax, chest tube, digital drainage system

Abbreviation List:

CI confidence interval

Introduction

The optimal procedure for chest tube removal has long been a subject of debate among both surgeons and pulmonologists.¹ Digital drainage devices have contributed to greater consensus regarding the appropriate timing and conditions for chest tube removal.¹ Unlike analogue drainage devices, digital devices provide an objective and continuous display of current and past air leaks, which has led to a reduction in the use of clamping trials.² It has been suggested that when a digital continuous recording drainage device is used and demonstrates the absence of (intermittent) air leakage, provocative clamping trials may no longer be necessary.³

Clamping trials continue to be employed in clinical practice even when digital drainage devices are used. This practice is often driven by expert opinion, entrenched habits, and concerns over a potential recurrent pneumothorax. Nonetheless, clamping trials require additional time, may lead to prolonged patient discomfort, longer hospital stay, and subsequently incur increased costs.⁴

There are no prospective studies evaluating clamping trials prior to chest tube removal with digital drainage systems. One prospective study assessing analogue drainage systems in patients with traumatic pneumothorax reported no difference in the rate of recurrent pneumothoraces between patients who underwent clamping prior to chest tube removal and those where no preceding intervention was performed (10% vs. 4.5%, respectively).⁵

We hypothesize that chest tube removal based solely on data derived from digital drainage systems is an acceptable approach compared to supplementary clamping trials preceding chest tube removal in patients treated for pneumothorax or following lung surgery.

Methods

Trial design

This study was conducted as a single-center, open label, non-inferiority, randomized controlled trial. Ethical approval for the study was granted by the Medical Research and Ethics Committee of Isala Clinics (approval number: 230403), and all participants provided written informed consent. Adults 18 years of age or older requiring chest tube drainage after pulmonary resection surgery or surgical pleurodesis, or for primary or secondary (hydro)pneumothorax were eligible for inclusion. Patients were included from the nursing ward at Isala hospital, Zwolle, the Netherlands. Exclusion criteria were: the use of analogue chest tube drainage systems, pleural effusion as the primary indication for chest tube placement, the presence of pleural empyema, suspected chest tube malfunction, or the use of invasive ventilation during chest tube removal. A schematic representation of the trial design is provided in Supplemental Figure 1.

Randomization and trial procedures

Patients were randomized on a 1:1 basis and assigned to either the Clamping Group (control) or the No-Clamping Group (intervention). Groups were stratified according to chest tube indication (non-

surgical chest tube placement for pneumothorax, surgical pleurodesis for recurrent pneumothorax, or post-pulmonary resection surgery). A web-based randomization system (ResearchManager) guaranteed concealment of allocation. Blinding of treatment was not possible due to the nature of the randomized treatment approaches. Following allocation, all subsequent treatments in both groups were recorded. Patients in both groups were followed for 30 days after chest tube removal. The Thopaz+ (Medela, Switzerland) digital chest drainage system was used in all patients.

Both treatment groups received standard of care which comprised of daily evaluation of digital chest tube drainage systems during morning rounds, as standard in our hospital. Chest tubes were eligible for removal when airflow was < 20ml/min and fluid drainage was < 250ml, both over a period of 24 hours.⁶

For the Clamping Group, once the aforementioned criteria were met, a baseline chest X-ray was obtained for future comparison and the chest tube was subsequently clamped. If a recent chest X-ray (obtained within 24 hours prior) was available and displayed no pneumothorax, the pre-clamping chest X-ray was omitted on the condition the patient had remained clinically stable. A follow-up chest X-ray was performed at least 4 hours after initiating the clamping trial. Chest tubes were removed if the follow-up chest X-ray showed a stable or no pneumothorax. In the No-Clamping Group, chest drains were removed immediately once the criteria for airflow and fluid drainage were fulfilled and a baseline chest X-ray was obtained. The intervention being the omission of a clamping trial. In both groups, a control chest X-ray was ordered the day following chest tube removal. If the patient was already discharged, this was performed in an outpatient setting. Chest X-ray was performed earlier if a patient developed new symptoms indicating possible recurrent pneumothorax (e.g. pain, dyspnea, hypoxemia).

Chest tubes were removed at end-expiration in both groups while the patient performed a Valsalva maneuver. The treating physician was required to document the procedure as either uncomplicated, exhibiting a possible air leak during removal, or showing a definite air leak during removal. In cases of recurrent pneumothorax requiring further intervention, patients would receive standard of care upon chest tube removal irrespective of their initial original group assignment.

Outcomes

The primary outcome was the percentage of patients who required chest tube reinsertion within 24 hours following chest tube removal due to recurrent ipsilateral pneumothorax. Secondary outcomes included the total incidence of recurrent ipsilateral pneumothorax within 24 hours and within 30 days, regardless of the need for intervention, the duration of chest tube drainage in days, the length of hospitalization following chest tube placement, and number of 'positive clamping trials' with progressive pneumothorax and subsequent unclamping of the chest tube. A pneumothorax after chest tube removal was defined as an increase in the distance between the lung margin and the chest wall at the level of the hilum of more than 2 centimeter (in accordance with British Thoracic Guidelines⁸, or alternatively an increase in the distance between the lung apex to the cupola of more than 3 centimeter (in accordance with the American College of Chest Physicians.⁹

Sample size and statistical analysis

The available literature on this topic is limited. Only one prospective controlled trial exists which used an analogue drainage system in a somewhat dissimilar population: traumatic pneumothorax. This study reported no significant difference in the rate of recurrent pneumothorax necessitating reintervention between patients after clamping trials or after evaluation of the device alone (10 vs. 4.5%, resp., p-value 0.15). Using these results and a web-based sample size calculator with a one-sided alpha of 2.5% and a non-inferiority margin of 10 percentage points, it was determined that a total of 88 participants (44 per group) were required to achieve a power of 80%. In the absence of an established non-inferiority margin, the study group concluded that a success rate of 90% in the Clamping Group (10% events) compared to an 80% success rate in the No-Clamping Group (20% events) would be deemed acceptable by both clinicians and patients. This margin reflects a difference that is unlikely to impact clinical decision-making or patient outcomes, balancing rigor with feasibility.

A per-protocol analysis with absolute risk differences served as the primary analysis to assess the outcomes for patients who adhered strictly to their assigned groups. In addition, an as-treated analysis including cross-overs, and an intention-to-treat (ITT) analysis, which included all randomized patients based on their original group allocation, were conducted. Absolute risk differences for the primary outcome were calculated for each analysis to provide a comprehensive understanding of the results. Non-inferiority was concluded if the upper bound of the two-sided 95% confidence interval for the absolute risk difference between the experimental and control treatments was less than the non-inferiority margin. Categorical data were presented as n(%) and continuous data as mean(±sd) or median(range), depending on the distribution. Statistical comparisons were made using the independent samples T-test for normally distributed data and the Mann-Whitney U test for nonnormally distributed data. For paired non-normally distributed data a Wilcoxon Signed Ranks test was employed. All statistical analyses were carried out using SPSS Statistics version 25.0.

Results

Patients and treatments

Between September 2022 and May 2024, a total of 92 patients were randomized in this study. Of these, nine patients were excluded post-randomization: four patients did not receive the treatment as per their assigned group, three were excluded due to chest tube malfunction, one was excluded due to a complicated chest tube removal that did not comply with the study protocol, and one patient was lost to follow-up. Among the four patients who received a treatment inconsistent with their allocation, one (2.2%) patient was assigned to the Clamping Group but did not undergo the clamping trial, while three (7.1%) patients in the No-Clamping Group underwent a clamping trial despite their allocation. Consequently, a total of 83 patients were included in the per-protocol analysis: 44 patients in the Clamping Group, whereby the clamping procedure was performed, and 39 patients in the No-Clamping Group, whereby the clamping procedure was omitted (Figure 1). One patient, who died from unrelated causes six days after chest tube removal with a normal chest X-ray obtained 24 hours after removal, was not included in secondary outcomes at 30 days. Baseline characteristics of the patients are detailed in Table 1.

Figure 1. Enrollment and Outcomes.

Primary outcome:

The primary outcome of patients requiring chest tube reinsertion within 24 hours after chest tube removal for recurrent ipsilateral pneumothorax occurred in 0 of 44 patients (0.0%) in the Clamping Group (control) and in 1 of 39 patients (2.6%) in the No-Clamping Group (intervention) (risk difference, 2.6 percentage points; 95% confidence interval (CI), –2.4 to 7.5) (Figure 2, Supplemental Table 1). The upper boundary of the 95% confidence interval was within the non-inferiority margin of 10 percentage points.

Figure 2. Absolute risk differences for recurrent ipsilateral pneumothorax with a non-inferiority margin of 10 percentage points, per-protocol analysis.

Secondary outcomes

The total number of patients with pneumothoraces, irrespective of the need for reintervention within 24 hours, was three in the Clamping Group (6.8%), and two in the No-Clamping Group (5.1%) (risk difference, -1.7 percentage points; 95%CI, -11.9 to 8.5).

The number of patients requiring chest tube reinsertion within 30 days after chest tube removal for recurrent ipsilateral pneumothorax occurred in 0 of 44 patients (0.0%) in the Clamping Group and in 1 of 38 patients (2.6%) in the No-Clamping Group (risk difference, 2.6 percentage points; 95%CI, % - 2.5 - 7.7). The total number of patients with pneumothoraces irrespective of the need for reintervention within 30 days was three in the Clamping Group (6.8%), and two in the No-Clamping Group (5.3%) (risk difference, -1.6 percentage points; 95%CI, % -11.8 - 8.7) (Supplemental Table 1).

In 6 (13.6%) patients in the Clamping Group, the initial clamping trial was unsuccessful, with progressive pneumothorax during clamping of the chest tube, necessitating unclamping and resumption of chest tube drainage. All six patients with a positive clamping trial had repeated clamping trials in the following days as determined by the treating physician, after which the chest tubes were removed without a recurrent ipsilateral pneumothorax. In one of these patients the chest-tube was removed despite a positive clamping trial, a recurrent ipsilateral pneumothorax did not occur.

In the ITT analysis one additional pneumothorax requiring intervention within 24 hours occurred in the No-Clamping Group after complicated chest tube removal, resulting in a risk difference of 4.3 percentage points (95%CI, -1.5 – 10.0), and was therefore inconclusive regarding the primary outcome. The total number of patients with pneumothoraces, irrespective of the need for reintervention within 24 hours, was three in the Clamping Group (6.7%), and three in the No-Clamping Group (6.4%) (risk difference, -0.3 percentage points; 95%CI, -10.4 to 9.8) (Supplemental Table 2 and Supplemental Figure 2). An as-treated analysis, allowing for cross-over of patients, yielded similar findings regarding non-inferiority as in the primary per-protocol analysis for pneumothorax within 24 hours or 30 days (Supplemental Table 3, Supplemental Figure 3). The four cross-overs included: one patient assigned to the Clamping Group, where the treating physician omitted the clamping trial due to fluid production as the only reason for prolonged chest tube drainage; and three patients in the No-Clamping Group, where the treating physician considered a clamping trial necessary (in two cases due to persistent low-flow air leaks, and in one case due to

incomplete lung expansion). None of these four patients developed a pneumothorax after chest tube removal. One patient, for whom a clamping trial was performed despite a persistent low-flow air leak, had a positive clamping trial, as expected. This patient, who had a primary pneumothorax, subsequently underwent surgical pleurectomy and bullectomy. Following the procedure, the chest tube was removed without a clamping trial, and no recurrent pneumothorax was observed during follow-up.

The chest tube remained in situ for a median of three (1-21) days in the No-Clamping Group and three (1-32) days in the Clamping Group (P=0.567). The median length of hospitalization following chest tube placement was four (1-35) days in the No-Clamping Group and five (1-35) days in the Clamping Group (P=0.751). Three patients (7.7%) in the No-Clamping Group and five patients (11.4%) in the Clamping Group were managed with a chest tube (at least in part) in an outpatient setting.

The median pneumothorax size, as measured from the apex in millimeters, was 7 (0–61) before and 8 (0–62) after chest tube removal in the Clamping Group (P = 0.123). In the No-Clamping Group, the median pneumothorax size was 7 (0–55) before and 9 (0–55) after chest tube removal (P = 0.610). The change in pneumothorax size did not alter between the No-Clamping Group and Clamping Group (P = 0.117) (Supplemental Table 4).

Discussion

This study aimed to evaluate the safety of chest tube removal without clamping trials in patients treated for post-lung surgery or pneumothorax, utilizing digital drainage systems. Our results indicate that the omission of clamping trials is not inferior to the traditional clamping method in preventing recurrent pneumothorax requiring chest tube reinsertion, thereby supporting the hypothesis that data from digital drainage systems alone can safely guide chest tube removal.

The length of hospital stay and the time to chest tube removal did not differ significantly between the groups and can therefore not be used as additional arguments for waiving clamping trials. Lung collapse following clamping, with subsequent unclamping of the chest tube, occurred in a clinically significant proportion of patients (13.3%), whereas no similar instances of pneumothoraces were observed in the No-Clamping Group. This finding suggests that clamping trials may have a potentially provocative effect and underscore the potential challenges, as unsuccessful attempts may result in prolonged chest tube use and patient discomfort in this subgroup.

One prospective study⁵ and three retrospective studies¹¹⁻¹³ have previously evaluated the utility of clamping trials. None of these studies utilized digital drainage devices, and the patient populations varied from traumatic to spontaneous pneumothoraces. Consistent with our findings, three out of four studies reported no significant difference in the rates of recurrent pneumothorax between patients who underwent clamping (5.9-10%) and those who did not (4.5-7.4%) before chest tube removal. ^{5,9,11} Interestingly, these studies also reported lower rates of recurrent pneumothorax after chest tube removal without clamping trials than would be expected based on the number of progressive pneumothoraces during clamping trials in the clamping groups (9.7-11.7%). In contrast, one retrospective study involving trauma patients found fewer pleural drainage procedures within 30 days of follow-up when clamping was performed prior to chest tube removal (13(6%) vs. 33 (12%)).¹²The results of the retrospective studies must be interpreted with caution because significant bias due to patient selection cannot be excluded.

Our results might have significant implications for clinical practice. The traditional use of clamping trials is rooted in a conservative approach to avoid recurrent pneumothorax. However, this study shows that reliance on digital drainage system data eliminates the need for clamping trials, thereby streamlining the workflow and number of imaging studies. The unexpectedly high need to unclamp chest tubes in 13.6% of patients emphasizes the importance of a cautious approach to clamping trials, as they may result in delayed chest tube removal and increased patient discomfort. While we can only speculate, we propose that the provocative effects observed during clamping may be due to a 'false air leak', where increased negative intrapleural pressure during normal breathing draws air from the chest tube incision or system, despite appropriate dressings. Alternatively, while a slow air leak is considered, its clamping-specific occurrence makes this less likely.

Patients recovering from surgical pleurodesis for pneumothorax may need a different strategy. Since pleurodesis takes at least several days to develop¹⁴, any pneumothorax, either due to chest removal or clamping, in this early adhesing period could theoretically compromise the effectiveness of this invasive procedure. Our subgroups were too small for separate analysis of patients after surgical pleurodesis. However, an alternative approach such as obligatory chest tube drainage for a yet to determine post-operative period might mitigate the risk of chest tube removal procedures.

Several limitations must be acknowledged. The single-center design of the study may limit generalizability. The selection of a 10% non-inferiority margin reflects an acceptable clinical threshold informed by prior studies and expert consensus, but was not directly validated through patient consultation. The smaller observed difference (only 1 event in the No-Clamping Group versus 0 in the Clamping Group, which represented a 2.6 percentage points difference for the primary outcome) suggests that the study may have been conservatively powered. Although the results support noninferiority, future studies with larger sample sizes may ensure sufficient power to do subgroup analyses and detect rare adverse events, these should incorporate patient engagement to ensure clinically meaningful thresholds that reflect both professional and patient priorities. The predominance of post-lung resection cases in the study limits its applicability to non-surgical pneumothorax patients. While stratifying by chest tube indication reduces some variability, further research targeting distinct etiological groups is necessary to validate these results across different patient populations, such as post-chemical pleurodesis, which was not studied here. While digital drainage systems demonstrate clear clinical advantages, the question of cost-effectiveness warrants consideration, particularly given the significant upfront investment associated with these systems. Additionally, some protocol deviations occurred, with four patients undergoing procedures contrary to their initial allocation. Subgroup analysis of these deviations revealed no discernible impact on pneumothorax recurrences rates, suggesting that the deviations did not significantly influence the study's conclusions.

In conclusion, this study provides additional evidence that chest tube removal based solely on digital drainage system data, without clamping trials, is as safe as the traditional method with clamping. This approach not only maintains patient safety but also has the potential to enhance patient comfort and reduce the number of imaging studies.

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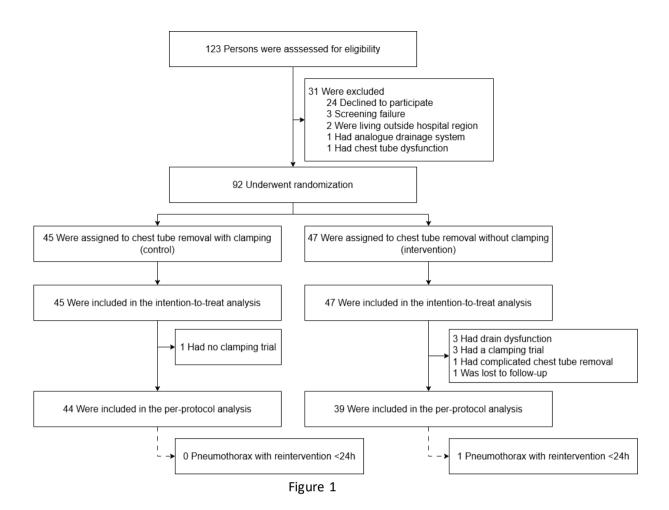
Characteristic	No-Clamping Group (N=47)	Clamping Group (N=45)		
Mean age - yr	58.1±20.4	61.1±16.9		
Male sex - no.(%)	32(68.1)	28(62.2)		
Median body-mass index - kg/m2(range)	26(17-34)	26(17-43)		
Smoking history - no.(%) Never Current Former	11(23.4) 9(19.1) 27(57.4)	9(20.0) 14(31.1) 22(48.9)		
Comorbidities - no.(%) Active malignancy Hypertension COPD Vascular disease Diabetes mellitus Asthma Sleep apnea Heart failure Pulmonary fibrosis Pneumothorax - no.(%) Previous ipsilateral pneumothorax	31(66.0) 17(36.2) 8(17.0) 7(14.9) 6(12.8) 5(10.6) 2(4.3) 1(2.1) 0(0.0)	31(68.9) 18(40.0) 11(24.4) 7(15.6) 5(11.1) 5(11.1) 3(6.7) 3(6.7) 1(2.2)		
Previous ipsilateral pneumothorax with chest tube Previous ipsilateral pleurodesis procedure	3(6.4) 1(2.1)	3(6.7) 0(0.0)		
Initial airflow* - no.(%) 0-20 ml/min 20-100 ml/min 100-1000 ml/min > 1000 ml/min	19(40.4) 15(31.9) 10(21.3) 3(6.4)	23(51.1) 10(22.2) 11(24.4) 1(2.2)		
Chest tube diameter - no.(%) < 16 Ch > 16 Ch	9(19.1) 38(80.9)	8(17.8) 37(82.2)		
Median chest tube suction level (after placement) - cm H2O (range) -2 to -7 -8 -9 to -15	-8(-122) 3 (6.4) 40 (85.1) 4 (8.5)	-8(-122) 9 (20.0) 30 (66.7) 6 (13.3)		
Median chest tube suction level (before removal) - cm H2O (range) -2 to -7 -8 -9 to -15	-8(-152) 6 (12.8) 34 (72.3) 7 (14.9)	-8(-152) 9 (20.0) 30 (66.7) 6 (13.3)		

33(70.2)	32(71.1)
28(84.8)	24(75.0)
3(9.1)	4(12.5)
2(6.1)	4(12.5)
6(12.8)	5(11.1)
6(100.0)	5(100.0)
8(17.0)	8(17.8)
5(62.5)	5(62.5)
3(37.5)	3(37.5)
	28(84.8) 3(9.1) 2(6.1) 6(12.8) 6(100.0) 8(17.0) 5(62.5)

Table 1. Demographic and Clinical Characteristics of the Patients at Baseline.

^{*}Initial average airflow after chest tube placement, not including high flow in the first minutes caused by lung expansion.

[†]Non-surgical chest tube placement for either primary or secondary pneumothorax.



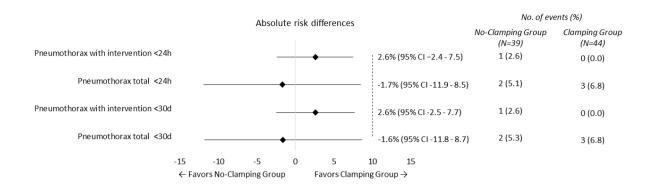
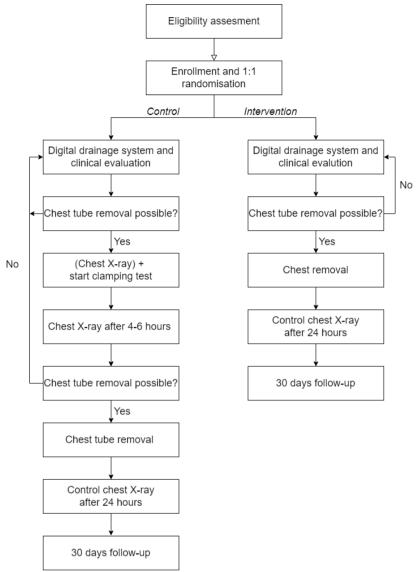


Figure 2

Supplemental material



Supplemental Figure 1. Schematic representation of the trial design.

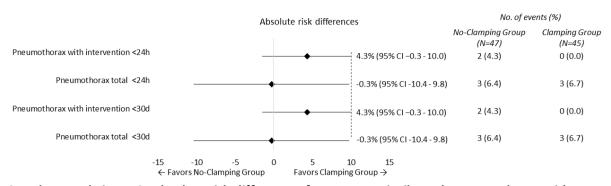
	No-Clamping	Clamping	Absolute Risk difference
	Group	Group	(95% CI)
	(N=39)	(N=44)	
	no. of events (%)		
Pneumothorax with intervention <24h	1 (2.6)	0 (0.0)	2.6% (-2.4 - 7.5)
Pneumothorax total <24h	2 (5.1)	3 (6.8)	-1.7% (-11.9 - 8.5)
Pneumothorax with intervention <30d*	1 (2.6)	0 (0.0)	2.6% (-2.5 - 7.7)
Pneumothorax total <30d*	2 (5.3)	3 (6.8)	-1.6% (-11.8 - 8.7)

Supplemental Table 1. Primary and secondary outcome, per protocol analysis.

^{*}One patient excluded in the No-Clamping Group; N=38.

	No-Clamping Group (N=47)	Clamping Group (N=45)	Absolute Risk difference (95% CI)
	no. of ev		
Pneumothorax with intervention <24h	2 (4.3)	0 (0.0)	4.3% (-1.5 - 10.0)
Pneumothorax total <24h	3 (6.4)	3 (6.7)	-0.3% (-10.4 – 9.8)
Pneumothorax with intervention <30d	2 (4.3)	0 (0.0)	4.3% (-1.5 - 10.0)
Pneumothorax total <30d	3 (6.4)	3 (6.7)	-0.3% (-10.4 – 9.8)

Supplemental Table 2. Primary and secondary outcome, intention-to-treat analysis.

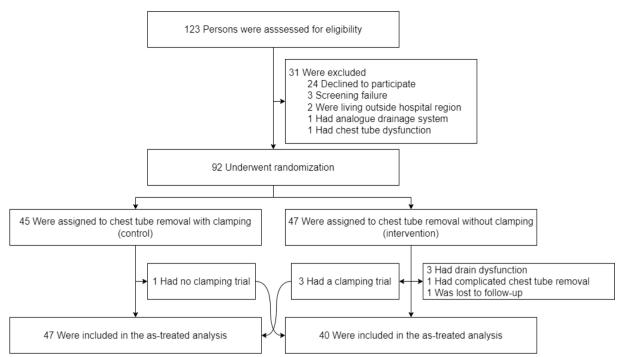


Supplemental Figure 2. Absolute risk differences for recurrent ipsilateral pneumothorax with a non-inferiority margin of 10 percentage points, intention-to-treat analysis.

	No-Clamping	Clamping	Absolute Risk difference
	Group	Group	(95% CI)
	(N=40)	(N=47)	
	no. of events (%)		
Pneumothorax with intervention <24h	1 (2.5)	0 (0.0)	2.5% (-2.3 - 7.3)
Pneumothorax total <24h	2 (5.0)	3 (6.4)	-1.4% (-11.1 - 8.3)
Pneumothorax with intervention <30d*	1 (2.6)	0 (0.0)	2.6% (-2.4 - 7.5)
Pneumothorax total <30d*	2 (5.1)	3 (6.4)	-1.3% (-11.1 - 8.6)

Supplemental Table 3. Primary and secondary outcome, as-treated analysis.

^{*}One patient excluded in the No-Clamping Group; N=39.



Supplemental Figure 3. Enrollment and Outcomes for as-treated analysis.

Pneumothorax	*Apex before	*Apex after	Difference	†Hilum before	†Hilum after	Difference
	Median(range)	Median(range)	(P)	Median(range)	Median(range)	(P)
No-Clamping Group (mm)	7(0-55)	9(0-55)	0.610	0(0-11)	0(0-15)	0.144
Clamping Group (mm)	7(0-61)	8(0-62)	0.123	0(0-10)	0(0-20)	0.317

Supplemental Table 4. Pneumothorax measured before and after chest tube removal for separate study groups.

^{*} As pneumothorax is measured by British Thoracic Society

[†] As pneumothorax is measured by the American College of Chest Physicians