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Clamping trials prior to thoracostomy tube removal and the need for subsequent invasive pleural drainage

James C. Becker [a], Scott A. Zakaluzny [a], Benjamin A. Keller [a], Joseph M. Galante [a], Garth H. Utter [a, b, *]

[a] Department of Surgery, University of California, Davis, USA
[b] Department of Surgery Outcomes Research Group, University of California, Davis, USA

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ABSTRACT

Background: There is little evidence supporting or refuting clamping trials, a period of clamping thoracostomy tubes prior to removal. We sought to evaluate whether clamping trials reduce the need for subsequent pleural drainage procedures.
Methods: We conducted a retrospective cohort study of trauma patients who underwent tube thoracostomy during 2009–2015. We compared patients who underwent clamping trials to those who did not, adjusting for confounders. The primary outcome was subsequent ipsilateral pleural drainage within 30 days.
Results: We evaluated 214 clamping trial and 285 control patients. Only two of 214 patients failed their clamping trial and none developed a tension pneumothorax [0.0% (95% CI 0.0–1.7%)]. Clamping trials were associated with fewer pleural drainage procedures [13 (6%) vs. 33 (12%); adjusted OR 0.41 (95% CI 0.20–0.84)].
Conclusions: A clamping trial prior to thoracostomy tube removal seems to be safe and was associated with less likelihood of a subsequent pleural drainage procedure.

Background

Modern thoracostomy tubes for drainage of traumatic pneumothoraxes and hemothoraxes were introduced during World War II and the conflict in Korea,[1,2] and have since become commonplace in the treatment of thoracic injures. Despite the recognized efficacy of these tubes in removing gas and blood from the pleural space, problems can occur after tube removal. As many as 30% of patients develop residual or recurrent pneumothorax or hemothorax after thoracostomy tube removal.[3–6] Reports vary as to how many of these are clinically significant, but one group has reported that 20% of patients who have a thoracostomy tube removed underwent placement of another tube.[6]

Multiple studies have assessed the impact of various factors on complications following thoracostomy tube removal, including patient characteristics,[4,7] positive pressure ventilation,[8] and the use of water seal versus suction[9]; however, the optimal timing and technique of tube removal remains controversial. Some authors have advocated thoracostomy tube clamping trials[10–12]—a brief period of tube clamping prior to possible removal—noting that it simulates tube removal and may identify subtle re-accumulation of intra-pleural gas that would otherwise be missed. This is proposed to reduce the need for re-intervention to drain pneumothoraxes after thoracostomy tube removal. In a 2001 Delphi consensus statement of the American College of Chest Physicians on management of spontaneous pneumothorax, a majority of panellists advocated clamping trials prior to removing thoracostomy tubes.[13] Conversely, some eschew clamping trials, citing concern for development of a tension pneumothorax.[12]

Prior to 2013, it was common practice at our institution for patients with a thoracostomy tube for traumatic injuries to undergo a 4-h clamping trial prior to tube removal. If patients developed respiratory distress or hemodynamic changes during this time, or

Abbreviations: IDP, invasive drainage procedure; ISS, Injury Severity Score; AIS, Abbreviated Injury Scale; IQR, interquartile range.

* Corresponding author. Department of Surgery, University of California Davis, Medical Center, 2335 Stockton Blvd., Rm. 5027 North Addition Office Bldg., Sacramento, CA, 95817, USA.
E-mail addresses: jamesxbecker@gmail.com (J.C. Becker), szakaluzny@ucdavis.edu (S.A. Zakaluzny), bakeller@gmail.com (B.A. Keller), jmgalante@ucdavis.edu (J.M. Galante), ghutter@ucdavis.edu (G.H. Utter).

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had a new or worsened pneumothorax on a chest radiograph at the end of the trial, the tube was unclamped and placed back to suction. In 2013, this practice was mostly abandoned due to perceptions that the clamping trials were frequently negative and that there was insufficient evidence regarding their efficacy or safety. Because of this change in practice, we could compare patients who underwent clamping trials to those who did not, with similar care in most other regards. We sought to compare these groups to determine if clamping trials decreased the need for an invasive drainage procedure (IDP) on the ipsilateral chest after thoracostomy tube removal. We hypothesized that clamping trials would reduce the risk of subsequent IDP.

Methods

Study design and population

In accordance with the protocol approved by the University of California, Davis Institutional Review Board, we conducted a retrospective cohort study of patients who had at least one thoracostomy tube placed for traumatic injuries, comparing the rate of complications among those who underwent a clamping trial prior to removing the tube versus those who did not.

We reviewed records of all patients at the University of California, Davis, Medical Center diagnosed with traumatic hemothorax or pneumothorax from July 2009 to March 2015. We included patients who were treated with one or more large-bore (external diameter 22 French or greater) polyvinyl chloride thoracostomy tubes. We excluded prisoners, children younger than 14 years of age, patients who were endotracheally intubated and ventilated with positive pressure at the time of tube removal, those whose initial tube was not a large-bore polyvinyl chloride tube (e.g., pigtail catheter), patients who died or were transferred out of our hospital prior to tube removal, patients for whom the thoracostomy tube was removed inadvertently, and those who had their tube(s) placed during a thoracic operation. For patients with more than one thoracostomy tube, we considered only the last thoracostomy tube to be removed eligible for inclusion to focus on the most salient circumstances for outcome assessment (subsequent length of stay and imaging utilization) and avoid challenges with non-independence of observations (among patients with bilateral tubes).

Thoracostomy tube management

While the management of thoracostomy tubes was not strictly standardized across the study period, patients were generally considered candidates for tube removal 48–72 h after insertion if there was no air leak for at least 24 h and no pneumothorax (or only a very small one that was not enlarging) visible on a radiograph from the same day.

We compared subjects documented to have undergone a clamping trial to those not documented as such ("control"). We used the time of clamping or tube removal, respectively, as the index time point. We defined a clamping trial as a period of four to 6 h during which the thoracostomy tube remained in situ and was completely occluded with a clamp, followed by a chest radiograph prior to releasing the clamp.

Patients in the control group typically underwent a trial of water seal, of varying durations, prior to removal of the thoracostomy tube. The technique of thoracostomy tube removal was not standardized during the study period, though the general practice at our center is to remove tubes rapidly at end-inspiration while simultaneously covering the insertion site with an occlusive dressing. Clinicians obtained a chest radiograph 6 h after tube removal to evaluate for any pneumothorax.

Data collection

We collected information on age, sex, mechanism of injury, indication for thoracostomy tube placement, Injury Severity Score (ISS), chest Abbreviated Injury Scale (AIS) score, thoracostomy tube external diameter, timing of thoracostomy tube removal, and results of clamping trials. We reviewed all progress notes and chest radiographs within 24 h after clamping trials to assess for harm directly attributable to the clamping trials.

Outcomes

We assessed any ipsilateral IDP—defined as insertion of any thoracostomy tube or catheter (any type and diameter), thoracentesis, or thoracic operation—within 30 days as the primary outcome. Secondary outcomes included: death, recurrent or worsened pneumothorax or effusion not requiring drainage, subsequent length of hospital stay, subsequent time the thoracostomy tube remained in place, number of subsequent chest radiographs, and subsequent use of chest computed tomography scan within 30 days.

Indications for imaging were at the discretion of the treating physicians. We assessed outcomes based on all of our center's records (inpatient and outpatient), but we did not attempt to contact patients for this study to assess outcomes that may have occurred at other centers within 30 days. [A separate review of 280 patients with thoracostomy tubes removed at our center during 2007–2012 identified only five patients (<2%) who underwent a subsequent IDP at another hospital within 30 days of tube removal (unpublished data).]

We defined the presence and progression of pneumothoraxes based on the attending radiologist's interpretation of the imaging. Small, stable pneumothoraxes present at the index time point that persisted on the post-removal radiograph were not considered recurrent. We relied on real-time assessment by treating physicians to determine failure of clamping trials, based on documentation of clinical stability of the patient and the appearance of the post-clamping trial radiograph.

Analysis

We analysed differences in baseline characteristics between the clamping trial and control groups using Student's t-test and the chi-square test. We used multivariable logistic regression to evaluate the relationships between clamping trial status and dichotomous outcomes. We used linear regression to evaluate subsequent time the thoracostomy tube remained in place (expressed as the mean difference with exposure) and Poisson regression to evaluate subsequent length of hospital stay and number of subsequent chest radiographs (expressed as incidence rate ratios, i.e., the factor increase or decrease associated with exposure). We considered age, sex, mechanism of injury, chest AIS score, ISS, pneumothorax and/or hemothorax as indications for thoracostomy tube placement, chest tube size (external diameter), and duration of the tube at the index time point as potential confounders. We constructed the regression model by including covariates that changed the primary endpoint's odds ratio from univariate analysis by 5% or more.

To assess the possibility that the threshold for different types of IDP interventions differed between the clamping trial and control groups, we evaluated the association of clamping trial status with pigtail catheter IDPs and thoracostomy tube IDPs separately. We opted not to consider calendar time as a potential confounder in the main analysis because the use and non-use of clamping trials overlapped only modestly; however, to address whether changes over time in the threshold for performing an IDP might have

contributed to any observed association between clamping trial status and IDPs, we repeated the main analysis adjusted for calendar year as a categorical variable. Among patients who underwent an IDP for a recurrent pneumothorax, we measured the maximum distance between the lung edge and the chest wall ("pneumothorax size") on plain anteroposterior chest radiographs and compared it between groups.

Based on an assumed risk of IDP of 20% in the absence of a clamping trial, we planned to be able to detect a reduction in the absolute risk of IDP to no more than 10% with 80% power and an α level of 0.05 if we compared 200 clamping trial patients to 200 control patients. We report data as the mean ± standard deviation for normally distributed data or the median and interquartile range (IQR) for skewed data. We set alpha at 0.05 for all tests.

Results

A total of 731 patients underwent placement of a thoracostomy tube for traumatic injury during the study period. Of these, 499 patients met inclusion criteria, including 214 who underwent a clamping trial and 285 who did not (Fig. 1).

Baseline characteristics of both groups were similar with respect to age (Fig. 2), sex, and mechanism of injury, though the clamping trial group had lower ISS (19 ± 9 versus 23 ± 12), chest AIS (3.3 ± 0.7 versus 3.5 ± 0.8), and percentage of patients with hemothorax as an initial indication for tube placement (41% versus 53%) (Table 1).

One patient of the 214 in the clamping trial group developed dyspnea and hypoxemia after starting the clamping trial, and this resolved with unclamping the tube. No patients suffered any apparent hemodynamic consequences (suggesting tension physiology) from the clamping trial [0/214, or 0.0% (0.0–1.7% 95% CI)]. Two patients who underwent a clamping trial failed the clamping trial: the aforementioned patient with hypoxemia, and another who developed an asymptomatic pneumothorax while the tube was clamped. Each of these two patients had their thoracostomy tube left in place for an additional 48 h before undergoing a subsequent successful clamping trial and tube removal.

Thirteen patients in the clamping trial group and 33 patients in the control group required an IDP, the primary outcome. The median (IQR) length of time from the index time point to IDP was 1 day (0, 2.5 days) in the clamping trial group and 1 day (0, 3 days) in the control group. On univariate analysis, clamping trials were predictive of a decreased need for ipsilateral thoracic drainage (OR 0.49, 95% CI 0.25–0.96). After adjusting for age and chest AIS, clamping trials remained associated with a decreased likelihood of IDP (OR 0.41, 95% CI 0.20–0.84) (Table 2).

The majority of IDPs were performed for recurrent pneumothoraxes [29 (63%)]; retained hemothorax or empyema [7 (15%)] and recurrent effusion [10 (22%)] were less frequent indications. The modality of IDP differed between the clamping trial and control groups, with pigtail catheters utilized more frequently in the control group (Table 3). In unadjusted analysis, clamping trials were associated with decreased pigtail catheter use (OR 0.28, 95% CI 0.08–0.97) but no difference in use of large-bore thoracostomy tubes (OR 1.19, 95% CI 0.45–3.14). Adjustment for age and chest AIS score nominally attenuated these relationships, with adjusted ORs of 0.30 (95% CI 0.08–1.12) and 0.84 (95% CI 0.29–2.46), respectively. Adjustment of the main analysis for calendar year also attenuated the association of clamping trials with IDPs such that chance alone could explain the association (OR 0.55, 95% CI 0.18–1.68).

Among patients who underwent an IDP, the maximal pneumothorax size was similar whether the IDP involved a large-bore thoracostomy tube or a pigtail catheter [27 ± 17 mm versus 39 ± 30 mm, respectively, p = 0.17 (*t*-test); median 23 (IQR 16, 35) mm versus 29 (22, 33) mm, p = 0.27 (Mann-Whitney *U* test)]. Similarly, there was no difference in the size of pneumothoraxes requiring IDP between the clamping trial and control groups [23 ± 12 mm versus 37 ± 27 mm, p = 0.14 (*t*-test); 22 (16, 29) mm versus 28 (19.5, 39.5) mm, p = 0.17 (Mann-Whitney *U* test)].

After adjustment, clamping trials were associated with decreased likelihood of subsequent chest computed tomography use (OR 0.49, 95% CI 0.25–0.94) and an increased length of time until thoracostomy tube removal (difference of 0.38 days, 95% CI 0.29–0.47 days) (Table 2). Of 54 patients who had a computed tomography scan within 30 days, 19 (35%) had an IDP; in comparison, of 445 patients who did not have a scan, 27 (6%) had an IDP. Among

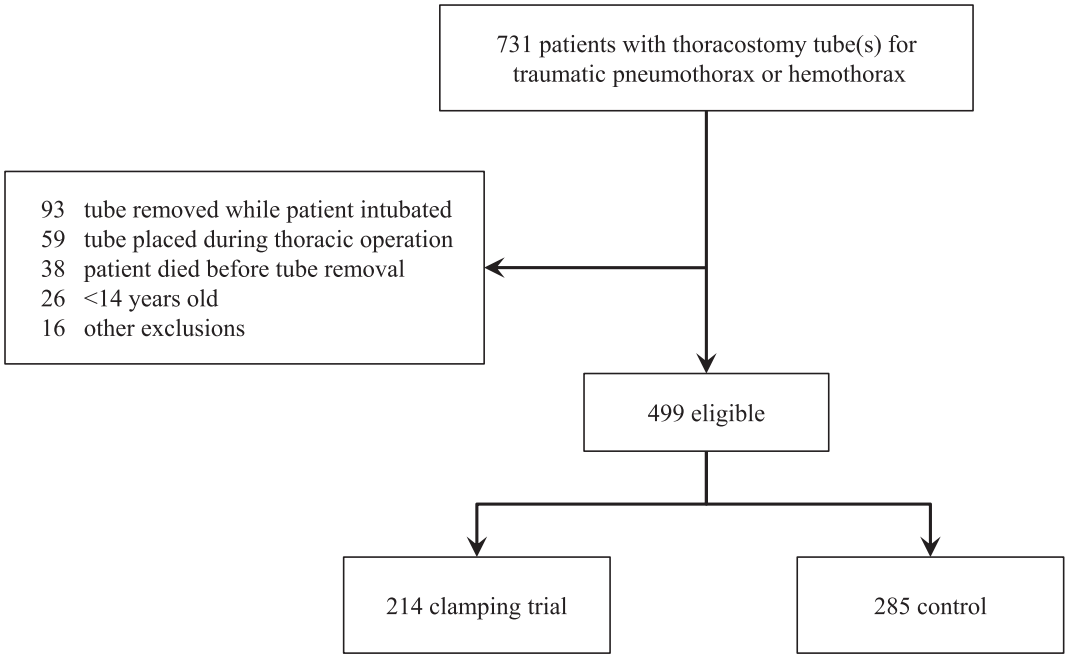

Fig. 1. Flow diagram of study patients.

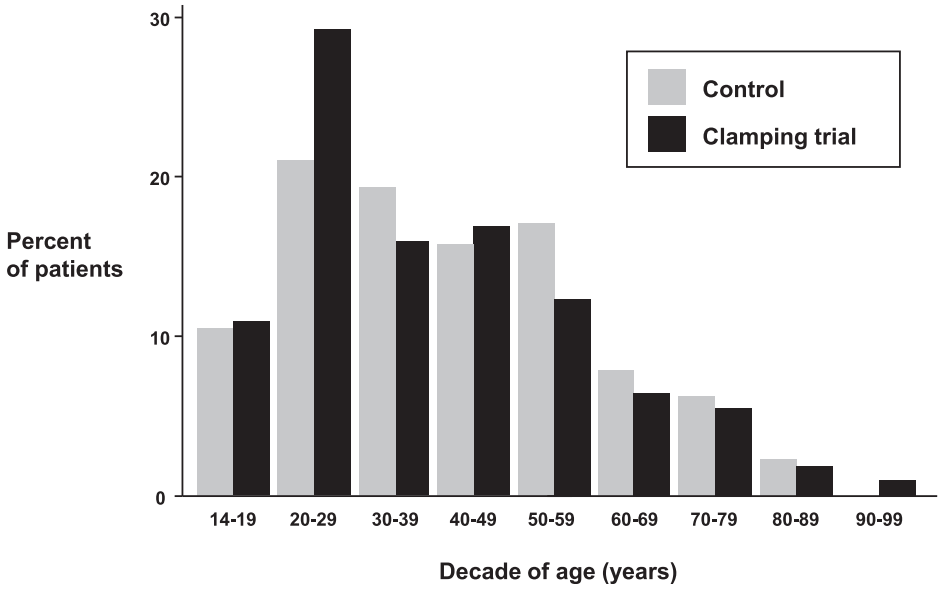

Fig. 2. Histogram of the age of study patients, by exposure status.

Table 1
Baseline characteristics of the 499 patients included in the study.

Characteristics	Control (N = 285)	Clamping Trial (N = 214)	P-value
Age, years, mean ± SD	42 ± 18	39 ± 18	0.07
Age, years, median (IQR)	39 (28, 54)	35 (24, 50)	0.04
Male sex, n (%)	213 (75)	167 (78)	0.39
ISS, mean ± SD	23 ± 12	19 ± 9	<0.001
Chest AIS score, mean ± SD	3.5 ± 0.8	3.3 ± 0.7	<0.001
Penetrating injury, n (%)	83 (29)	69 (32)	0.45
Pneumothorax, n (%)	218 (77)	182 (85)	0.07
Hemothorax, n (%)	151 (53)	88 (41)	0.009
Thoracostomy tube external diameter, Fr, n (%)			0.01
22	0 (0)	1 (0.5)	
24	2 (1)	1 (0.5)	
28	24 (8)	9 (4)	
32	70 (24)	35 (16)	
34	0 (0)	1 (0.5)	
36	169 (59)	159 (74)	
Not documented	20 (7)	8 (4)	
Days from thoracostomy tube placement until the index time point, mean ± SD	5.1 ± 2.9	4.0 ± 2.0	<0.001

SD = standard deviation.
IQR = interquartile range.
ISS = Injury Severity Score.
AIS = Abbreviated Injury Scale.

Table 2
Association of clamping trials prior to thoracostomy tube removal with the primary and secondary study outcomes.

Outcome	Control (N = 285)	Clamping Trial (N = 214)	Unadjusted OR, difference, or IRR (95% C.I.)	Adjusted[a] OR, difference, or IRR (95% C.I.)
Ipsilateral invasive drainage procedure within 30 days, n (%)	33 (12)	13 (6)	0.49 (0.25–0.96)[b]	0.41 (0.20–0.84)[b]
Ipsilateral recurrent pneumothorax or effusion within 30 days, not requiring an invasive drainage procedure, n (%)	83 (29)	61 (28)	0.97 (0.66–1.44)[b]	0.87 (0.57–1.32)[b]
Chest computed tomography scan within 30 days, n (%)	40 (14)	14 (6)	0.43 (0.23–0.81)[b]	0.49 (0.25–0.94)[b]
Additional duration of tube, days, median (IQR)	0 (0, 0)	0.21 (0.17, 0.33)	0.39 (0.30–0.48)[c]	0.38 (0.29–0.47)[c]
Length of stay, days, median (IQR)	3.0 (1.0, 8.0)	2.2 (1.2, 5.3)	0.73 (0.68–0.78)[d]	0.78 (0.72–0.85)[d]
Chest radiographs within 30 days, median (IQR)	2 (2, 5)	3 (3, 4)	0.91 (0.84–0.99)[d]	0.91 (0.84–0.99)[d]
Death within 30 days, n (%)	0 (0)	0 (0)	–	–

OR = odds ratio.
IRR = incidence rate ratio.
CI = confidence interval.
IQR = interquartile range.
AIS = Abbreviated Injury Scale.
[a] Adjusted for age and chest AIS score.
[b] OR.
[c] Difference.
[d] IRR.

Table 3
Indications for different types of invasive drainage procedures (study primary outcome) among 46 patients who underwent such procedures.

Indication	Control Group					Clamping Trial Group				
	Thoracentesis	Pigtail drain	Thoracostomy tube	VATS	Thoracotomy	Thoracentesis	Pigtail drain	Thoracostomy tube	VATS	Thoracotomy
Effusion (n = 10)	1	3	0	3	0	0	1	1	1	0
Empyema/retained hemothorax (n = 7)	0	0	0	5	1	0	0	0	0	1
Pneumothorax (n = 29)	0	11	9	0	0	0	2	7	0	0
Total (n = 46)	1	14	9	8	1	0	3	8	1	1

VATS = video-assisted thoracoscopic surgery.
For patients who underwent more than one invasive drainage procedure, we enumerate only the most invasive such procedure per patient (with order of invasiveness increasing from left to right).

the 19 patients who had both a computed tomography scan and an IDP, 16 (84%) underwent the scan prior to the IDP, and this ratio did not differ between patients who had a clamping trial and those who did not.

Clamping trials did not predict the occurrence of pneumothoraxes or effusions that did not result in an IDP, but they were associated with modestly fewer chest radiographs and shorter length of hospital stay after the index time point. None of the patients died within 30 days.

Discussion

In this retrospective cohort study of patients with traumatic hemo- or pneumothoraxes, thoracostomy tube clamping trials were associated with less risk of an ipsilateral invasive drainage procedure within 30 days after tube removal. Among secondary outcomes, clamping trials were also associated with less likelihood of subsequent chest computed tomography scanning, slightly fewer chest x-rays, and shorter subsequent length of stay, all of which were likely associated with the circumstances that led to the primary outcome events. With clamping trials, thoracostomy tubes remained in place longer, though typically only for several hours. The incidence of pneumothorax or effusion not requiring drainage was similar to that of patients who did not undergo a clamping trial.

The ostensible rationale for clamping trials is that they detect clinically occult air leaks treatable by simply unclamping the tube, thus obviating the need for thoracostomy tube reinsertion. However, despite observing that clamping trials were associated with decreased likelihood of IDP, we identified only two patients who failed their clamping trial. This suggests two possibilities to us. One is that clamping trials reduce IDPs by some means other than revealing an occult air leak. For example, it is possible that the additional time tubes were in place with clamping trials (eight or more hours for 25% of patients) allowed greater healing and pleural apposition or that the small amount of extra attention that patients undergoing clamping trials received from nurses and physicians somehow reduced their subsequent risk of a pneumothorax or effusion requiring an IDP. The other main possibility is that the difference in IDP rates was due to other factors besides clamping trials, i.e., residual confounding.

Over the study period, the use of pigtail catheters and video-assisted thoracoscopic surgery for IDPs predominantly occurred among patients who did not undergo a clamping trial. We evaluated whether the increased rate of IDPs without clamping trials may have simply reflected confounding from a lower threshold to evacuate recurrent pneumothoraxes using pigtail catheters. However, we found that the size of pneumothoraxes treated with pigtail catheters was similar to (if not larger than) the size of those treated with reinsertion of a thoracostomy tube, and that the size of recurrent pneumothoraxes prompting an IDP was similar between patients who underwent a clamping trial and those who did not. (Because we could not accurately measure the size of fluid collections on plain chest radiographs, it was not feasible to similarly compare the size of fluid collections that prompted thoracostomy tube versus pigtail catheter placement or video-assisted thoracoscopic surgery.) The information on pneumothorax size suggests that the increased rate of IDP in the control group may not simply be attributable to more liberal use of pigtail catheters. To further evaluate potential confounding from secular trends, we also adjusted the primary analysis by calendar year. This weakened the association of clamping trials with decreased IDPs such that it no longer reached significance, suggesting that secular trends—including, possibly, different thresholds for placing pigtail catheters and performing video-assisted thoracoscopic surgery—for which we were otherwise unable to account may have contributed to the observed association.

Notably, no patients developed a tension pneumothorax or otherwise seemed to be harmed as the result of a clamping trial. With 214 observations, the upper bound of the 95% confidence interval for the likelihood of such harm was 1.7%. This lack of harm may reflect certain safeguards at our center: Clamping trials were not performed on patients undergoing positive pressure ventilation, thoracostomy tubes were on suction for an average of four days prior to clamping, clamping trials were only performed once the physician team thought it was appropriate to consider removing the tube, and both physicians and nurses had experience with clamping trials because of our center's sustained use of this practice. Taken together, our results suggest that clamping trials can be a safe and possibly effective means to reduce invasive drainage procedures after thoracostomy tube removal in trauma patients not on positive pressure ventilation.

While thoracostomy tube management has been the subject of multiple investigations examining the effects of timing,[14] drainage volume,[15] and patient-related factors[4,8] on complications after thoracostomy tube removal, we identified only two comparable studies examining the impact of clamping trials on the subsequent development of clinically significant pneumothoraxes or effusions.[11,16] In their retrospective review of 243 patients with traumatic pneumothorax or hemothorax, Funk et al. identified 134 patients who had a clamping trial of 6 h prior to thoracostomy tube removal according to a protocolized care pathway.[11] Similar to our findings, they only noted a single patient who required urgent intervention after thoracostomy tube clamping, and concluded that it was a safe intervention. Contrary to our findings, they reported good effectiveness of clamping trials in identifying subclinical air leaks, with a greater proportion of patients who developed recurrent pneumothoraxes or dyspnea during the clamping trial (9.7%) compared to our study (0.9%). This may have been due to other differences in tube management, e.g., the longer time interval without air leak we employed before considering patients eligible for clamping trials (24 versus 12 h). These investigators observed no difference in the likelihood of thoracostomy tube reinsertion in

patients who underwent clamping trials (6.7%) compared to those who did not (4.6%), though their study may have lacked sufficient power to identify a clinically important difference.

Rasheed et al. randomized 180 patients with thoracostomy tubes placed for trauma at a military hospital in Pakistan, to either a 6 h clamping trial or tube removal.[16] Although these investigators did not clearly distinguish between pneumothoraxes that occurred during the clamping trial versus after removal of the index thoracostomy tube, they described no difference in the occurrence of "recurrent pneumothorax" between the clamping trial and control groups (10% versus 4.5%, respectively).

Other aspects of our study were largely concordant with the existing literature. The proportion of patients in our study with pneumothorax or effusion after thoracostomy tube removal (29%) and the proportion requiring intervention (9.2%) were comparable to those reported in other studies.[4,6,11,17] Our center did not routinely use a standardized volume of tube drainage to determine appropriateness for removal, which is not inconsistent with the varying amounts of drainage, from 100 to 400 mL per 24 h, other investigators have used as a threshold for considering removal of thoracostomy tubes.[15,18–20]

There are several limitations of our study. The main concern is that, as an observational comparison, it may have been confounded. Although we accounted for differences between study groups in age, sex, mechanism of injury, ISS, chest AIS, indication for initial thoracostomy tube insertion, thoracostomy tube size, and duration of the tube at the index time point, other unknown or unmeasurable factors besides clamping trials may have explained the differences we observed. For example, due to the limited availability of relevant information, we could not account for pre-existing pulmonary disease or diminished functional reserve as potential confounding factors. However, in another study that involved substantial overlap with this study in participation, we identified a low rate of chronic obstructive pulmonary disease (2%), moderate rate of asthma (13%), and modest smoking history [median (IQR) of 0.3 (0, 10) pack-years],[21] suggesting that the likelihood of confounding from these characteristics might be low. Another limitation is that, although the clamping trial was well defined and consistent in implementation, the control group underwent water seal trials of varying duration, and incorporation of the rate of tube drainage into management was not standardized, introducing some heterogeneity. The indications for IDPs (as well as chest radiographs and computed tomography scans) were also not standardized, allowing variation at the treating physician's discretion. The decreased use of computed tomography we observed may have resulted directly from clamping trials, but it also may explain the decreased risk of IDP associated with clamping trials if decreased scanning caused fewer IDPs to occur.

Despite these shortcomings, the reduction in drainage procedures after clamping trials is a provocative, if tentative, finding. We can be fairly confident that in this patient population clamping trials can be safely performed, and it is possible that they also reduce the need for re-intervention after thoracostomy tube removal, conditions that are necessary to establish clinical equipoise for a rigorously conducted randomized trial evaluating the impact of a standardized clamping trial protocol.

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