


Presumptive antibiotics in tube thoracostomy for traumatic hemopneumothorax: a prospective, Multicenter American Association for the Surgery of Trauma Study

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Presented at the American Association for the Surgery of Trauma 77th Annual Meeting, San Diego, CA, September 2018.

Received 7 July 2019
Accepted 15 October 2019

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To cite: Cook A, Hu C, Ward J, et al. *Trauma Surg Acute Care Open* 2019;4:e000356.

ABSTRACT

Background Thoracic injuries are common in trauma. Approximately one-third will develop a pneumothorax, hemothorax, or hemopneumothorax (HPTX), usually with concomitant rib fractures. Tube thoracostomy (TT) is the standard of care for these conditions, though TTs expose the patient to the risk of infectious complications. The controversy regarding antibiotic prophylaxis at the time of TT placement remains unresolved. This multicenter study sought to reconcile divergent evidence regarding the effectiveness of antibiotics given as prophylaxis with TT placement.

Methods The primary outcome measures of in-hospital empyema and pneumonia were evaluated in this prospective, observational, and American Association for the Surgery of Trauma multicenter study. Patients were grouped according to treatment status (ABX and NoABX). A 1:1 nearest neighbor method matched the ABX patients with NoABX controls. Multilevel models with random effects for matched pairs and trauma centers were fit for binary and count outcomes using logistic and negative binomial regression models, respectively.

Results TTs for HPTX were placed in 1887 patients among 23 trauma centers. The ABX and NoABX groups accounted for 14% and 86% of the patients, respectively. Cefazolin was the most frequent of 14 antibiotics prescribed. No difference in the incidence of pneumonia and empyema was observed between groups (2.2% vs 1.5%, $p=0.75$). Antibiotic treatment demonstrated a positive but non-significant association with risk of pneumonia (OR 1.61; 95% CI: 0.86~3.03; $p=0.14$) or empyema (OR 1.51; 95% CI: 0.42~5.42; $p=0.53$).

Conclusion There is no evidence to support the routine use of presumptive antibiotics for post-traumatic TT to decrease the incidence of pneumonia or empyema. More investigation is necessary to balance optimal patient outcomes and antibiotic stewardship.

Level of evidence II Prospective comparative study

BACKGROUND

Thoracic injury has been shown to occur in approximately 60% of patients with trauma.¹⁻⁴ One in three patients with this type of injury will develop

a hemothorax, pneumothorax, or hemopneumothorax (HPTX).¹⁻⁴ Although no statistics are available for the number of post-traumatic tube thoracostomies (TT) performed in the USA annually, this commonly performed procedure remains the first-line treatment for drainage of the pleural cavity.

It is well documented that TTs placed in the trauma setting are associated with increased hospital length of stay (LOS), morbidity, and cost.^{5,6} In addition, over the past 40 years evidence on the topic of antimicrobial drugs administered prior to TT to prevent infectious complications has accumulated in the literature. Numerous researchers have advocated for the routine use of presumptive antibiotics (ABX).⁷⁻¹⁰ Conversely, others have demonstrated little difference in outcomes following use of ABX.¹¹⁻¹⁵ Despite the combined efforts of the surgical community, the benefits of presumptive antibiotics for reducing infectious complications remain controversial.^{11,12,16-20}

The Eastern Association for the Surgery of Trauma (EAST) Practice Management Guidelines Committee released an update in 2012 to previously published guidelines to address physician questions and concerns related to presumptive antibiotic use in TT placement.¹⁵ The Committee recommended neither for nor against the use of ABX to reduce the incidence of empyema and pneumonia following post-traumatic TT. In addition, a recommendation was made for a future “large and likely multicenter, randomized, controlled trial” to advance the study of routine practice of presumptive antibiotics in TT for traumatic HPTX.¹⁵

The aim of the current study was to resolve the controversy regarding the need for antibiotics when TTs are placed in the setting of traumatic HPTX. As such, a multicenter study was undertaken.

METHODS

A prospective, observational, multicenter study was conducted under the sponsorship of the American Association for the Surgery of Trauma (AAST) at 23 Level I and II trauma centers. The AAST Multi-Institutional Trials Committee approved the study protocol and each participating site obtained

separate approval from its institutional review board prior to participation. Blunt and penetrating injuries for all patients resulting in tube thoracostomy (TT) for traumatic HPTX were identified between December 1, 2013 and November 15, 2016. Inclusion criteria were: patients of any age and presence of HPTX as determined at the radiologists' or surgeon's discretion and by standard of care at each individual site. Patients who were receiving antibiotics prior to their injury were excluded from the study as were patients where data points were not available or missing, or the indication for TT was left blank.

Intervention groups

Patients were classified into two groups, those who received antibiotics for TT (treatment) and those who did not (control), ABX and NoABX, respectively. Those who received antibiotics for reasons other than the TT (ie, open fractures, other procedure/surgeries) on day zero or an unknown day were not included in the primary analysis but were added later for the sensitivity analysis. Subjects who were given antibiotics aside from TT at least 1 day after injury were included in all analysis, since taking antibiotics later could be a consequence of taking, or not taking, the presumptive antibiotics on the day of injury, and hence was an intermediate variable. Patients were managed according to standard of care and at the surgeons' discretion with regard to observation, antibiotic choice and start time, treatment course, complication management, need for additional thoracostomy tube(s), video-assisted thoracostomy, or image-guided percutaneous drainage of intra-abdominal fluid or thoracostomy.

Patient characteristics and outcomes

Demographic and outcome data collected included the following: age, Glasgow Coma Score on arrival, Injury Severity Score and the corresponding Abbreviated Injury Scores (AIS), mechanism of injury, treating facility (American College of Surgeon [ACS] level (I or II), state, both), trauma center population (adult, pediatric, and both), trauma admissions per year (less than 1500, 1500–3000, and greater than 3000), indication for the initial TT placement, TT details (provider placing, location of placement), ABX type, ABX aside from TT, complications from injury (empyema, retained HPTX, pneumonia, *Clostridium difficile* colitis), days on mechanical ventilation, intensive care unit (ICU) LOS, hospital LOS, and death.

Empyema was defined as having a positive pleural culture or pus within the pleural space. Pneumonia was defined as a new or evolving infiltrate on chest radiograph with any of the following: (1) purulent sputum (2) positive blood culture, or (3) positive sputum culture or protected brush specimen $>10^5$ or bronchoalveolar lavage $>10^6$ or 10^{20} (institution-specific) colony-forming units. Participating centers used volunteer registrars to collect data on standardized data collection forms and enter into an online data collection portal resource supported by the AAST was used to store patient data.

Statistical analysis

Continuous variables were summarized by median and IQR and were compared between two subgroups of patients (those treated by ABX for TT vs untreated controls) using the Wilcoxon rank-sum test. Categorical variables were summarized by frequency and proportion, and were compared between the two groups by the χ^2 test or Fisher's exact test. Logistic regression models were fitted with receiving presumptive ABX treatment for TT as the outcome, and with patient demographics and characteristics of the injury, the treating trauma center and

the surgery as covariates. A propensity score was estimated as the probability of receiving presumptive ABX treatment for TT. A subject's propensity score represents the probability of treatment selection taking into consideration covariates observed at baseline. This score allows for the estimation of causal treatment effects when working with observational or non-randomized data and helps to improve the precision of the estimate of treatment effect. Histograms were used to examine the propensity scores within the treatment and the control groups. Nearest neighbor matching was used to match one treated subject with one untreated control. Subjects out of the common support were excluded where the common support is the range of propensity scores for both groups inclusive of only those cases with an appropriate matched control. Balance in the characteristics, as well as the propensity score, was checked before and after the matching by summarizing the mean for continuous variables and proportions for categorical variables.

Outcomes

The primary outcome measures of in-hospital empyema and pneumonia, along with the secondary outcome measures of ICULOS, hospital LOS, ventilation days, death, pneumonia or death, and occurrence of *C. difficile* colitis were compared between treated and control matched pairs using McNemar's test (binary outcomes) or Wilcoxon signed-rank test (count outcomes). The OR for each binary outcome measure and antibiotics treatment was estimated using logistic regression with random effects of matched pairs and trauma centers. The rate ratio for each count outcome and antibiotic treatment was estimated by negative binomial regression with random effects for matched pairs and trauma centers. A 95% CI was estimated for each measure of association. In sensitivity analysis, the marginal ORs and rate ratios for the outcome measures and antibiotic treatment were estimated using generalized estimating equations (GEE) fitted on the full cohort, adjusted for all characteristics of patients, trauma centers, injury, and surgery, with each trauma center treated as a cluster. CIs and p values were based on the robust SE. All tests were two-sided at the 0.05 significance level. All analyses were conducted using the statistical software package R (V.5.3),²¹ R Foundation for Statistical Computing, Vienna, Austria. URL: <https://www.R-project.org/> and propensity score matching was conducted using the R package MatchIt (V.3.02).²²

RESULTS

Study population

Initially, data were received on 2406 subjects. In all, 37 subjects were excluded due to missing data or pending status. A total of 482 subjects who received antibiotics for reasons other than TT on hospital day zero or an unknown hospital day were excluded. Following these exclusions, a total of 1887 subjects were included in the primary analysis. Within this group, 272 patients (14%) were in the ABX group and 1615 (86%) were in the NoABX group. Table 1 summarizes the demographic data of patients included in the primary analysis.

In comparing the two groups, many variables were significant. The most commonly administered presumptive antibiotic in this study was cefazolin. Other antibiotics used included vancomycin, clindamycin, piperacillin–tazobactam, meropenem, ampicillin, ampicillin–sulbactam, cefepime, nafcillin, ertapenem, gentamycin, levofloxacin, ceftriaxone, and metronidazole. Whereas hospitals with greater than 3000 admissions per year were more likely to use cefazolin ($p=0.017$), no evidence

Table 1 Trauma center, patient and injury characteristics, and TT details by antibiotics status

	No antibiotics*		Antibiotics*		P value†
N	1615	(85.6)	272	(14.4)	
Age	45	(27, 59.5)	34	(24, 54)	<0.01
Male	1249	(77.3)	214	(78.7)	0.68
Mechanism of injury					
Blunt	1207	(74.7)	162	(59.6)	<0.01
Penetrating	408	(25.3)	110	(40.4)	
GCS on arrival					
Mild (13-15)	1157	(71.6)	210	(77.2)	0.12
Moderate (9-12)	78	(4.8)	8	(2.9)	
Severe (≤8)	380	(23.5)	54	(19.9)	
Intubation	761	(47.1)	100	(36.8)	<0.01
ISS					
0-14	727	(45)	117	(43)	0.80
16-24	420	(26)	75	(27.6)	
25+	468	(29)	80	(29.4)	
Indication for TT placement					
Hemothorax	313	(19.4)	60	(22.1)	0.15
Pneumothorax	788	(48.8)	141	(51.8)	
HPTX	514	(31.8)	71	(26.1)	
TT provider					
Attending	273	(16.9)	34	(12.5)	0.02
Other	1172	(72.6)	231	(84.9)	
Unknown	170	(10.5)	7	(2.6)	
TT location					
Emergency Department /trauma bay	1184	(73.3)	198	(72.8)	<0.01
Floor	54	(3.3)	4	(1.5)	
ICU	211	(13.1)	28	(10.3)	
Operating room	113	(7)	41	(15.1)	
Unknown	53	(3.3)	1	(0.4)	
Trauma center designation					
American College of Surgeons verified trauma center	458	(28.4)	53	(19.5)	0.01
State	34	(2.1)	5	(1.8)	
Both	1123	(69.5)	214	(78.7)	
Trauma center level					
1	1583	(98)	256	(94.1)	<0.01
2	32	(2)	16	(5.9)	
Trauma center population					
Adult	614	(38)	103	(37.9)	0.14
Pediatric	17	(1.1)	7	(2.6)	
Both	984	(60.9)	162	(59.6)	
Trauma admissions per year					
<1500	208	(12.9)	37	(13.6)	0.08
1500-3000	1016	(62.9)	186	(68.4)	
>3000	391	(24.2)	49	(18)	

*Median (IQR) for continuous variables and count (percentage) for categorical variables. †Fisher's exact test or χ^2 test for categorical variables and Wilcoxon rank-sum test for continuous variables; the unknown category, if present, is excluded from the testing procedure. GCS, Glasgow Coma Score; HPTX, hemopneumothorax; ICU, intensive care unit; ISS, Injury Severity Score; TT, tube thoracostomy.

Table 2 Comparison of outcome measures in the matched sample

	No antibiotics*	Antibiotics*	P value†
	n=272	n=272	
Empyema	4 (1.5)	6 (2.2)	0.75
Pneumonia	27 (9.9)	42 (15.4)	0.07
ICULOS	2 (0.6)	3 (0.9)	0.02
Hospital LOS	7 (4,14)	8 (4,16)	0.31
Ventilation days	0 (0,3)	1 (0,5)	0.08
Death	29 (10.7)	24 (8.8)	0.58
Death or pneumonia	54 (19.9)	61 (22.4)	0.52
<i>Clostridium difficile</i> colitis	3 (1.1)	2 (0.7)	>0.99

*Count (percentage) for binary outcomes and median (IQR) for count outcomes. †McNemar's test for binary outcomes and Wilcoxon signed-rank test for count outcomes. ICU, intensive care unit length of stay.

of differences were noted between the ABX and NoABX groups when comparing prescribing providers or trauma center level.

Matched sample analysis: differences in outcomes

The nearest neighbor matching method was used to match the 272 patients in the ABX group with individual controls in the NoABX group at a 1:1 ratio (total n=544 in the resulting groups). Tables summarizing variables for treatment and control groups before and after matching are available in the supplement. Balance in the characteristic variables was much improved after matching. Primary and secondary outcomes were compared between the matched pairs (table 2). The only significant difference was increased ICULOS in the ABX group (p=0.02). There were no significant differences in the primary outcomes of empyema and pneumonia or the secondary outcome measures of hospital LOS, ventilation days, death, death or pneumonia, and *C. difficile* colitis.

Estimated ORs for each binary outcome measure and antibiotics treatment based on the logistic regression with mixed effects and the rate ratio for each count outcome and antibiotic treatment based on negative binomial regression with random effects are given in table 3.

Antibiotic treatment demonstrated a positive but non-significant association with risk of pneumonia (OR 1.61; 95% CI: 0.86 to 3.03; p value=0.14). The results also showed no association between antibiotic treatment and any of the other primary or secondary outcomes.

Table 3 Measure of association for primary and secondary outcomes

	OR (95% CI)	P value
Empyema	1.51 (0.42 to 5.42)	0.53
Pneumonia	1.61 (0.86 to 3.03)	0.14
Death	0.55 (0.25 to 1.22)	0.14
Pneumonia or death	1.17 (0.77 to 1.77)	0.46
<i>Clostridium difficile</i> colitis	0.65 (0.09 to 4.48)	0.66
	Rate ratio (95% CI)	P value
ICULOS	1.35 (0.93 to 1.96)	0.11
Hospital LOS	1.15 (0.95 to 1.40)	0.15
Ventilation days	1.43 (0.86 to 2.39)	0.17

Logistic regression for binary outcomes and negative binomial regression for count outcomes, both with random effects of matched pairs and trauma centers. ICULOS, intensive care unit length of stay.

Table 4 Sensitivity analysis: adjusted measures of association based on full cohort

	OR (95% CI)	P value
Empyema	1.35 (0.58 to 3.16)	0.49
Pneumonia	1.54 (0.97 to 2.46)	0.07
Death	0.9 (0.45 to 1.81)	0.78
Pneumonia or death	1.31 (0.76 to 2.25)	0.32
<i>Clostridium difficile</i> colitis	0.58 (0.24 to 1.41)	0.23
	Rate ratio (95% CI)	P value
ICULOS	1.34 (1.17 to 1.54)	<0.0001
Hospital LOS	1.14 (1.05 to 1.23)	0.0019
Ventilation days	1.33 (1.01 to 1.75)	0.042

Adjusted estimates of marginal ORs and rate ratios based on generalized estimating equations fitted on the full cohort, with each trauma center treated as a cluster. CIs and p values were based on the robust SE. ICULOS, intensive care unit length of stay.

Sensitivity analysis

A sensitivity analysis was performed on the full cohort of 1887 subjects. The marginal ORs and rate ratios for the outcome measures and antibiotic treatment were estimated using GEEs fitted on the full cohort, with each trauma center treated as a cluster. CIs and p values were based on the robust SE. The results of the sensitivity analysis were similar to those of the primary analysis (tables 4 and 5).

There remained no significant association between antibiotic use and all binary outcomes, including the primary outcomes of infectious complications of pneumonia or empyema. However, antibiotic treatment was associated with increased ICULOS, hospital LOS, and ventilator days.

DISCUSSION

In this first of its kind large multi-institutional observational study, no evidence was found that presumptively administered antibiotics decreased the incidence of empyema or pneumonia. Currently, practice patterns regarding the use of antibiotic therapy for post-traumatic TT vary widely among providers and include routine, selective, or no antibiotic treatment. Rates of observed antibiotic usage vary throughout the literature. In 2000, the EAST Practice Management Guidelines Work Group recommend a first-generation cephalosporin with duration of no longer than 24 hours.²³ The Western Trauma Association

Table 5 Sensitivity analysis: adjusted measures of association based on full cohort

	OR (95% CI)	P value
Empyema	1.35 (0.48 to 3.77)	0.56
Pneumonia	1.54 (0.97 to 2.46)	0.068
Death	0.9 (0.5 to 1.63)	0.74
Pneumonia or death	1.31 (0.86 to 2.01)	0.21
<i>Clostridium difficile</i> colitis	0.58 (0.12 to 2.87)	0.51
	Rate ratio (95% CI)	P value
ICULOS	1.52 (1.24 to 1.87)	0.0001
Hospital LOS	1.18 (1.05 to 1.31)	0.0041
Ventilation Days	1.6 (1.19 to 2.15)	0.0016

Adjusted estimates of ORs and rate ratios based on generalized linear models fitted on the full cohort. ICULOS, intensive care unit length of stay.

published a similar recommendation in 2014 that underscored the need for Gram-positive peri-operative antimicrobial usage of less than 24 hours.²⁴ In the current observational study, 14.4% of patients received antibiotics for TT. The lower rate of antibiotic use in this study may reflect population variances or changing individual or institutional practice patterns. Antibiotic selection was highly varied across providers and institutions.

Infectious complications following TT have been extensively studied. The most significant infections following post-traumatic TT include empyema and pneumonia. Empyema and pneumonia can be introduced (1) iatrogenically from chest tube placement, (2) may result from pleural violations, or (3) result from diaphragmatic disruptions from the initial trauma, retained hemothorax, or hematogenous spread from other sources.²³ In 2006, Sanabria *et al* published a meta-analysis of five randomized controlled trials and reported pneumonia in 16% of patients who were not treated with antibiotics and 6.6% of patients were treated.⁹ The authors also reported empyema in 7.6% of patients who were not treated and 1.1% of patients who were treated.⁹ Several large observational studies have previously been performed; however, these have primarily been single center studies that followed institutional guidelines for selective antibiotic therapy.^{19–25} In these cases, empyema rates were reported at 3.1% and 1.6%.^{19–25} In the present study's sensitivity analysis, there was no significant difference in the primary outcomes. The NoABX group demonstrated an observed infectious complication rate lower than reported in the meta-analysis from Sanabria *et al*.⁹ Conversely, the ABX group had higher rates than observed in the meta-analysis. This is may be the result of patient selection bias for treatment with antibiotics.

Challenges with interpreting the existing body of literature as a whole include variation in the antibiotic type and duration, as well as use of non-standard dosing regimens.¹⁵ Studies have also used varied and non-standard definitions for diagnosing empyema and pneumonia.²³ Pulmonary contusion, multiple chest tube placement, retained HPTX, duration of TT, length of ICU stay, laparotomy, and thoracic AIS have all been shown to be independent risk factors for post-traumatic empyema development.^{13–18, 25} These factors, as well as other possible cofounders including location of chest tube placement and qualification of the operative provider are inconsistently controlled for in the literature and clinical practice. Similar cofounders and limitations may explain why there remains conflicting evidence on this topic.

A large randomized controlled trial published by Maxwell *et al* as well as several observational studies have found no difference in infectious complications between groups who received antibiotics and those who did not.^{11–12, 16–20} However, contrary to these findings, there is a substantial volume of literature which has demonstrated decreased infectious complications with the use of presumptive antibiotics.^{7–10, 26–32} In this study, there were no significant differences in pneumonia or empyema between the ABX and NoABX groups. Concordant with the present study, there was a borderline association between antibiotic use and pneumonia in the measure of association analysis which did not reach statistical significance.

Although ICULOS was significantly different between groups in univariate comparison, no outcomes differed significantly in multivariable analysis. The multivariable model demonstrated a modestly increased rate ratio for hospital LOS among the ABX patients. Mortality occurred in 9%–10% of each group, with no significant differences observed in either the primary or sensitivity analysis. The final secondary outcome measured was *C. difficile* colitis. This was an infrequent occurrence, with two

and three patients diagnosed in the ABX and NoABX groups, respectively.

Limitations

This study was subject to many of the known limitations of an observational design. While nearest neighbor matching was used to help reduce bias due to unmeasured cofounders, including provider-level preferences of antibiotic use with TT, as well as antibiotic selection and duration. As such, it is possible providers were more likely to prescribe antibiotics for patients deemed at higher risk for infection. Next, the wide array of antibiotics prescribed among the ABX group may have obscured the results such that the odds and rate ratios reported here represent the means of widely varying treatment effects. Insufficient data were available to assess dose–response relationships between outcomes of interest and patients who received ABX for TT. Finally, the results of this study may reflect a type II error. However, bias also skews results toward the null. Thus, it is not possible to quantify the contribution of either limitation to the lack of differences we observe. Despite these limitations, to our knowledge, this is the largest study to date to prospectively assess the use of antibiotics for post-traumatic TT. It is difficult to reconcile a topic in which both randomized controlled studies and large observational studies across decades continue to return conflicting results. Ultimately, prescribing antibiotics may not reduce pneumonia or empyema. Nonetheless, these results should be interpreted with caution.

CONCLUSION

There is no evidence to support the routine use of presumptive antibiotics for post-traumatic TT to decrease the incidence of pneumonia or empyema. As we continue to seek methods of decreasing infectious complications without increasing risk of antibiotic resistance, it will become increasingly important to isolate the role of antibiotics in appropriate patient populations.

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Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All data relevant to the study are included in the article.

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