

Does Administration of Parenteral Antibiotic Reduces the Incidence of
Intrathoracic Infections in Patients Sustaining Penetrating Stab Wound to the
Chest after Close Tube Thoracostomy? A Randomized Clinical Trial

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Abstract

Objective: To determine whether the administration of presumptive antibiotic therapy reduces the incidence of intrathoracic infections in patients requiring closed tube thoracostomy and to generate a locally-generated, site- and disease-specific guideline that will result in decreased duration and cost of confinement for such cases. **Method:** Prospective, double-blind, placebo-controlled administration of Penicillin and Normal Saline in patients requiring CTT. All patients without comorbidities sustaining penetrating SW with pneumothorax of less than six hours requiring CT insertion will be included in the study. Intrathoracic infections, cost, and hospital stay will be the outcome measures.

Results: Twenty seven (27) patients were enrolled. Fifteen (15) patients received PenG (Grp 1) and twelve (12) received NS (Grp 2). Twenty seven (27) patients, were admitted and underwent Chest tube Thoracostomy. There were two morbidities discovered, one (1) incidence of empyema and One (1) incidence of Pneumonia for the NS group (16.7%).

Conclusion: When compared with saline placebo, the administration of a parenteral antibiotic (PenG) to patients with pneumothorax secondary to penetrating stab wound significantly affects the incidence of intrathoracic infections but no difference in the length of hospital stay.

Keywords: Closed tube thoracostomy, antibiotics

Introduction

There are presently quite a number of data on the use of intravenous antibiotic therapy for patients requiring CTT for Traumatic Pneumothorax. However, further clinical evaluation is required since these data lacked a well-designed trials. Despite the lack of a well validated study, antibiotic use for these cases continue to be practice for the presumption that it will decrease the incidence of intrathoracic infection.

In our institution, PenG 5M units every 6 hours is the antibiotic use for these patients.

So, it is the aim of this study to produce a locally generated, site specific guidelines on the use of antibiotic therapy in patients requiring CTT for traumatic Pneumothorax.

It is the aim of this study to investigate whether non use of antibiotic will favorably affect outcome in patients operated on for Closed tube thoracostomy at Ospital Ng Maynila Medical Center, Department of Surgery. Establishment of a pathway can result in decreased hospital expenses and reduced duration of confinement.

Research Objectives

General Objective

To determine whether the administration of presumptive antibiotic therapy reduces the incidence of intrathoracic infections in patients requiring closed tube thoracostomy.

Specific Objective

To generate a locally-generated, site- and disease-specific guideline that will result in decreased duration and cost of confinement for such cases.

STUDY DESIGN

The study is a Prospective Randomized Single-Blinded Clinical Trial.

METHODOLOGY

A. Study Subjects:

1. Inclusion criteria:

- Patients who presented at Department of Surgery with Traumatic Pneumothorax of less than six hours after time of injury who are more than 12 y.o.but less than 60. and who have no other associated or concurrent medical conditions.
- With voluntary written informed parental consent to participate in the study and comply with the protocol.

2. Exclusion criteria:

- Patients who have previously consulted other hospitals and was given and/or previously self-medicated with oral/i.v. antibiotics prior to being admitted at OMMC
- Patients with concomitant finding of Hemothorax
- Patients whose ages fall outside of the inclusion criteria
- Patients with co-morbid conditions such as DM and on steroids.
- Those who refuse to give consent to participate in the study.

B. Sample Size:

All patient accrued during the initial 9 month period will be included for analysis.

C. Allocation:

All patients will go through the proposed management protocol except for those who did not give consent or were excluded by the criteria mentioned above.

D. Study Procedure:

1. Get a complete history and physical examination of patients who came in with penetrating chest wound.
2. Once the diagnosis of Pneumothorax is made, clinical or by xray, they will be informed of the study protocol.

3. Once the diagnosis is made, secure a voluntary written informed consent for participation in the study.
4. The patient is placed on NPO and intravenous line is inserted.
5. Fluid resuscitation will be given as the case requires.
6. CTT will be carried out based on the recommended operative technique of the department.

- i. CT French 36
- ii. Sterilized Minor set
- iii. Silk 0 strands
- iv. Standardized CT Bottle
- v. Leukoplast

- CTT will be done in the isolation room at the Surgery ER
- A repeat CXR upright will be carried out after CTT.

7. Randomization using the table of random numbers.

- i. Group A: Antibiotic Group

- PenG 5M units every 6 hours for 24 hours.

- ii. Group B: Placebo Group

- 5 cc of Distilled water every 6 hours for 24 hours.

-Blinding will be facilitated by the senior resident on duty. A standard 5 cc syringe will be used throughout the study.

-The SROD will prepare the Antibiotics and/or the Distilled water in a standardized manner.

-After the drugs has been prepared. It will be handed over to the junior resident on duty, who will be blinded as to what are the contents of the syringes. He will be the one responsible for the administration of the drugs.

-Drug preparation will be repeated at the surgery ward.

8. Tetanus prophylaxis and pain control will be given accordingly.
9. Patients will be followed up at the surgery ward. A repeat CXR-Upright 24 hours post op will be done. CT removal will depend on the latest CXR findings (Full expansion)
10. Clinical monitoring for signs of intrathoracic infection (fever, Chest findings, CXR findings) will be carried out.
11. Patients will be discharge on the following criteria:
 - i. fully expanded lung by CXR
 - ii. no evidence of infection
 - iii. no respiratory distress
12. Follow -up 2 weeks and 1 month post op.

RESULTS

Table 1. Sex Distribution.

Group	Male	Female
Group 1		1
(PenG)	14	
Group 2		0
(Placebo)	12	
Total	27	1

Table 2. Average hospital stay and postoperative complication.

Mean	Complications
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Average		
Hospital		
Stay		
Group A	4	None
Group B	3	2

Table 3. Morbidity

	Empyema	Pneumonia
Group A	None	None
Group B	1	1

Table 4. Average Cost

Mean Antibiotic Cost	
Group A	P300.00
Group B	P50.00

Discussion

Chest injury is a common problem in patients sustaining blunt or penetrating trauma. Thoracic wounds account for 20 to 25% of all trauma deaths (16,000) annually. Only 10 to 15% of all chest wounds require thoracotomy, whereas the remaining 85% can be managed with a closed tube thoracostomy. A major morbidity associated with this therapeutic device is empyema. The role of

prophylactic antibiotics in reducing the incidence of this complication is controversial.

The value of antibiotic prophylaxis for elective and urgent operations in surgical practice has been validated by many studies. For injured patients, the purpose and optimal duration of antibiotic use are less clear because there is no opportunity to administer the agent before bacterial contamination occurs. Antibiotics administered in this setting have been used traditionally for early presumptive therapy and thus are not truly prophylactic. The goal of this preventive therapy is the same as that of prophylaxis: to reduce the incidence of infectious complications following a therapeutic intervention.

Reasonable assumptions about the microorganisms most often encountered are used to guide the selection of antimicrobial agents. The primary goal of prophylactic antibiotic use in injured patients requiring tube thoracostomy is to reduce the incidence of empyema and its associated morbidity. A secondary goal may be a reduction of bacterial pneumonia, but the literature is difficult to interpret because of the variability in criteria used to make this diagnosis. An additional area of confusion in interpreting the results of various studies is the lack of clarity regarding pneumonia as a primary or secondary endpoint of prophylaxis.

Conclusion

According to the data presented, there is a significant difference in the complication rate (16.7%) for placebo and antibiotic group. Out of the twelve subjects enrolled in placebo group, two (2) develop intrathoracic infection. One was empyema and the other was pneumonia.

Initial data presented favors administration of presumptive antibiotic therapy for patients undergoing close tube thoracostomy. However, this are inconclusive because of a limited sample size.

There was no significant difference in hospital stay at three to four days.

It is recommended by the authors to accrue and continue the study to increase sample size.

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