

Effects of a Simple Protocol on Infective Complications in Intensive Care Unit Patients Undergoing Percutaneous Dilatational Tracheostomy

Sydney Jacobs MB ChB, Abdul Mohsen Al Rasheed MBBS MSc MRCPATH,
Wadood Abdulsamat SMLSO PhD, Ali Al Barrak MBBS DTM&H,
Nasser Fawzan Al Omer MSc, David Tjan MD Drs, Mehrun Zuleika MB ChB,
Faham Ahmed MBBS, and Mushera Enani MD

In our intensive care unit we monitored infection in 228 patients who underwent percutaneous dilatational tracheostomy (PDT). In the first phase of the study 128 PDTs were performed during a 33-month period and there were 41 infection complications (nosocomial pneumonia, bacteremia with sepsis, and septic shock) in the perioperative period (immediately prior to and for 5 days after PDT). A significant risk factor among patients with nosocomial pneumonia was empirical administration of inappropriate antibiotics, compared to appropriate antibiotics (34% versus 4%, $p < 0.001$). In the second phase of the study (a 30-month period), a simple antibiotics protocol was prospectively applied to 100 PDT patients. The protocol virtually eliminated inappropriate antibiotic drug use immediately prior to PDT and contributed to a significant reduction in perioperative infective complications (pre-protocol 32% versus protocol 11%, $p < 0.001$). Key words: percutaneous dilatational tracheostomy, sepsis, nosocomial pneumonia, intensive care, infection control. [Respir Care 2003;48(1):29–37]

Introduction

Tracheostomy is one of the commonest surgical procedures. It is increasingly being performed in intensive care units (ICUs), at the bedside, as a percutaneous procedure, using a Seldinger technique.^{1,2} Recognized complications of conventional surgical tracheostomy include bleeding, infection, pneumothorax, subcutaneous emphysema, and tracheal stenosis. Compared to the surgical technique, per-

cutaneous dilatational tracheostomy (PDT) is reported to be safer, faster, less expensive, more economical as regards surgical and theatre time, and to have a lower rate of infection.^{3,4}

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Some reports have expressed concern about performing tracheostomy on ICU patients without antibiotic cover,⁵ in view of the known risk of bacteremia associated with airway instrumentation, the degree of risk being related to the amount of airway trauma.^{6,7} PDT involves repeated tracheal instrumentation in patients at high risk for upper airway colonization.⁸ It has also been shown that tracheostomy and changing the endotracheal tube are very common causes of nosocomial pneumonia in ICU patients.⁹

We noticed cases of nosocomial pneumonia occurring in the initial days following PDT and even a few cases of septic shock in the first 24 hours following PDT. Based on these observations and the report by Elatrous et al,⁹ who showed that tracheostomy was a major risk factor for nos-

Sydney Jacobs MB ChB, David Tjan MD Drs, Mehrun Zuleika MB ChB, and Faham Ahmed MBBS are affiliated with the Department of Anaesthesia and Intensive Care; Abdul Mohsen Al Rasheed MBBS MSc MRCPATH and Wadood Abdulsamat SMLSO PhD are affiliated with the Department of Microbiology; Nasser Fawzan Al Omer MSc is affiliated with the Department of Pharmacy; Ali Al Barrak MBBS DTM&H and Mushera Enani MD are affiliated with the Infectious Disease Unit, Department of Medicine; Riyadh Armed Forces Hospital, Riyadh, Kingdom of Saudi Arabia.

Correspondence: Sydney Jacobs MB ChB, Department of Anaesthesia and Intensive Care, X994 Riyadh Armed Forces Hospital, PO Box 7897, Riyadh 11159, Kingdom of Saudi Arabia. E-mail: sydney@nesma.net.sa.

ocomial pneumonia (univariate analysis, odds ratio = 18.6, $p = 0.00005$), we decided to ascertain the microbiological status and infection rates of our ICU patients. We analyzed data from 128 patients and found there were a substantial number of patients undergoing PDT who had nosocomial pneumonia, bacteremia with sepsis, and colonization with potential pathogens and who were receiving either no or inappropriate antibiotics at the time of PDT. We hypothesized that if all PDT patients had a clinical assessment and microbiological investigation several days prior to PDT, we could ensure appropriate antibiotic cover and reduce active infection immediately prior to and for several days after PDT. We developed a microbiology/antibiotic protocol and prospectively applied it to 100 patients who underwent PDT.

Methods

All our adult ICU patients considered to require elective tracheostomy were considered for PDT. We used the Ciaglia PDT set (William Cook Europe, Bjaeverskov, Denmark) and followed recent advice on technique.^{10,11} During the first part of the study (ie, before implementing the protocol) we used the multiple dilator tracheostomy set (C-PTS-100) to perform PDT. For the second part of the study (ie, during the protocol) we used the new Ciaglia single-dilator Blue Rhino set (C-PTIS-100-WC1-HC). Patients were excluded from tracheostomy for any of the following: endotracheal extubation likely within 7 days; infection or burns at the intended tracheostomy site; lesions obscuring the trachea anteriorly; severe acute respiratory distress syndrome; raised intracranial pressure; cardiovascular instability.

To reduce the incidence of nosocomial pneumonia, we encouraged a low gastric pH by intermittent feeding¹²⁻¹⁵ and avoiding drugs that raise gastric pH. We used sucralfate to protect the gastric mucosa and preserve normal gastric pH.¹⁶ Gastric pH was monitored daily with litmus paper (Whatman, Whatman International, Maidstone, United Kingdom) at the bedside with enterally fed patients at the end of the fasting period, and in patients receiving total parenteral nutrition. We fed all our enterally fed patients for 16 hours and then allowed an 8-hour fast.¹⁵ This strategy allowed the gastric mucosa time to establish an acidic milieu and reduced overgrowth with aerobic Gram-negative organisms. We fed all patients enterally, using a nasogastric tube if possible, and only resorted to total parenteral nutrition if enteral feeding was inappropriate or impossible. We recorded the mode of nutrition daily. None of our acutely critically ill patients had percutaneous endoscopic gastrostomy tubes inserted; those tubes were reserved for patients who were likely to require gastric feeding for many months, such as patients with severe neurological deficit. Attention to patient position was also

considered important, and we routinely kept our patients semi-erect.¹⁷ Endotracheal tubes were never routinely changed once the patient had been admitted to the ICU. Every patient had a central venous catheter, inserted via the subclavian vein (ie, infra-clavicular), and a silastic urinary catheter in situ at the time of PDT.

All patients undergoing PDT were fasted for at least 4 hours prior to the procedure. For the procedure we provided mechanical ventilation with 100% oxygen, sedation with propofol (1–2 mg/kg), analgesia with fentanyl (5 $\mu\text{g}/\text{kg}$), and muscle paralysis with atracurium (1 mg/kg). Airway management and anesthesia during the procedure was the responsibility of an anesthetist or respiratory therapist. Patients were placed at 20–30° head down, a rolled towel was placed between the shoulder blades for cervical extension, secretions in the oropharynx were removed by suction under direct vision with an indirect laryngoscope because aspiration of highly colonized oropharyngeal secretions above and around the endotracheal tube cuff is a main cause of nosocomial pneumonia.¹⁸ The endotracheal tube was repositioned so that the cuff was at the level of the larynx. A second doctor was responsible for fiberoptic bronchoscopy¹⁹⁻²¹ to confirm correct positioning of the PDT needle and wire during the procedure and to perform bronchial toilet immediately after PDT.

The protocol for this study was conducted in accordance with the ethical standards of the World Medical Association Declaration of Helsinki²² and was approved by the Research and Ethics Committee of our hospital. Informed consent was obtained from each patient's relatives.

The protocol for microbiological investigation in the first phase of this study (pre-protocol period) involved aseptic collection of blood for culture 1 hour prior to PDT and then immediately following the procedure. Further blood cultures were taken if clinically indicated. The method of taking blood cultures from a peripheral vein was by full aseptic technique, using 10% povidine iodine antiseptic solution. Lower respiratory tract (LRT) aspirate was collected immediately prior to PDT. Blind bronchial sampling for LRT collections was performed using a sterile catheter with a specimen trap kit (Model 534-16, Vygon, Ecouen, France).²³ The sensitivity of blind bronchial suctioning is significantly higher ($p < 0.05$) than that of protected sample brushings,²⁴ so we favor blind bronchial suctioning for diagnosis of nosocomial pneumonia.

In the second phase of this study (protocol period) we took blood samples for blood cultures and blind bronchial suctioning at least 3 days prior to the intended date of PDT. All patients were followed for 5 days after PDT to monitor clinical pulmonary infection score (CPIS).²⁵ Appendix 1 shows our method of assessing CPIS. The criterion for nosocomial pneumonia was a CPIS > 6 together with a pathogen cultured from the bronchial aspirate. Patients with CPIS ≤ 6 and bronchial pathogen were con-

sidered to be colonized and were not given antibiotics. A blood culture was defined as negative if there was no growth after 7 days. Bacteremia was defined as the presence of viable bacteria in the blood. Sepsis (systemic inflammatory response to infection) and septic shock were defined according to the American College of Chest Physicians/Society of Critical Care Medicine Consensus Conference.²⁶ The presence and type or absence of antibiotics were noted for every patient. We looked for infective complications for up to 5 days following PDT, including local wound infection, sepsis, septic shock, and pneumonia. We had determined the local bacterial spectra and presence of antimicrobial resistance in our patients prior to and during the course of this study to formulate an empirical antibiotic therapy policy.²⁷ During this study period all isolates from our ICU had their sensitivities to antibiotics recorded. An inappropriate antibiotic was defined as one given empirically for an infecting organism that was subsequently shown, by *in vitro* sensitivity testing, to be resistant to that antibiotic.

Mean arterial pressure and arterial oxygen saturation measured via pulse oximetry (S_{pO_2}) were monitored continuously in all patients. A plain anteroposterior chest radiograph was taken after PDT. A post-PDT S_{pO_2} decrease that necessitated a substantial ($> 20\%$) increase in the fraction of inspired oxygen from pre-PDT levels was regarded as an indication of either lung collapse or pneumothorax, and a clinical examination and repeat chest radiograph were immediately performed. Lung collapse not improved by physiotherapy was treated by flexible fiberoptic bronchoscopy and direct suction.

All clinically important noninfective complications related to the PDT were also noted. These included bleeding, lung collapse, pneumothorax, and failed PDT. Complications were deemed serious if they had the potential to prolong recovery or threaten the patient's life, and nonserious if not. Substantial bleeding was defined as hemorrhage that could not be controlled by conservative measures and that required blood transfusion and/or re-exploration.

All patients had the necessary data collected on ICU day 1 to assess the severity of illness via the Acute Physiology and Chronic Health Evaluation (APACHE II).²⁸ All patients were followed until hospital discharge or death.

In the pre-protocol group (128 patients), over a 33-month period, we found a perioperative PDT infection rate of 32% (41/128), which appeared to be partly related to a high incidence of inappropriate antibiotic use prior to PDT. Patients who received inappropriate empiric antibiotics had a significantly higher incidence of pneumonia than patients on appropriate antibiotics (34% [12/35] versus 4% [3/74], $p < 0.001$ by chi-square test). We anticipated that patients who at the time of PDT had active pneumonia, bacteremia with sepsis, or LRT colonization with potential pathogens, and who were receiving inappropriate or no

antibiotics were at greater risk than patients receiving appropriate antibiotics. We therefore designed a simple protocol that (1) focused on the importance of performing blood cultures and LRT specimens, and included clinical evaluation at least 72 hours before PDT, and (2) administered an appropriate antibiotic regimen prior to PDT, testing the antibiotic regimen's efficacy in the case of confirmed diagnosis of pneumonia or sepsis. Once it had been decided to perform PDT on a patient, blood culture and blind bronchoalveolar lavage were performed. PDT was then delayed for 72 hours to allow time for reporting of the microbiological findings, combined with clinical assessment, and the following microbiological protocol adhered to:

1. For patients with no obvious sepsis or pneumonia and negative blood and tracheal aspirate culture, no antibiotics were prescribed.

2. For patients with no obvious sepsis or pneumonia but a positive blood culture and/or positive pathogen culture from LRT, PDT was performed with appropriate antibiotic cover immediately before and for 24 hours following the procedure.

3. For patients with clinical sepsis and/or nosocomial pneumonia, if the microbiology findings and clinical status indicated that empirical antibiotic cover had been appropriate, PDT was performed. On the other hand, if the microbiology findings and clinical status suggested that the choice of antibiotics had been inappropriate, the antibiotics were changed and a further 72-hour delay was recommended, awaiting improvement.

We prospectively assessed the impact of this protocol on infection rate following PDT in 100 ICU patients. An additional change in ICU infection control procedures also occurred coincidentally during this period. We applied a tightening of care of intravascular lines, in keeping with the Hospital Infection Control Practices Advisory Committee.²⁹

Statistical Analysis

Results are expressed as mean \pm standard deviation, and differences were compared using the 2-tailed Student's *t* test and the F-ratio test. Proportions were evaluated using the Yates corrected chi-square test or Fisher's exact test when applicable. Differences were considered statistically significant if p was < 0.05 .

Results

Over a 33-month period (from November 1996 to July 1999) 135 patients required tracheostomy in our 18-bed ICU. Seven of these 135 patients (5%) were considered unsuitable for PDT because of anatomical problems (4 cases), thyroid tumor (1 case), and serious coagulopathy (2

ANTI-INFECTION PROTOCOL FOR PERCUTANEOUS DILATATIONAL TRACHEOSTOMY

Table 1. Characteristics of 228 Patients Who Underwent Percutaneous Dilatational Tracheostomy

Characteristics	Before Protocol (n = 128)	During Protocol (n = 100)	p*
Mean age (y ± SD)	56 ± 21	49.7 ± 23.4	0.04
Male (n)	105	63	0.001
Female (n)	23	37	
Total parenteral nutrition (%)	15 (12)	9 (9)	0.66
Patients with mean gastric pH > 3 (%)	25 (20)	19 (19)	0.52
Chronic ill health† (%)	59 (46)	37 (37)	0.18
Day 1 mean APACHE II score ± SD	18.8 ± 6.8	19.2 ± 6.6	0.35

*By Fisher's exact test, 2-tailed

†As defined by Knaus et al.²⁸

APACHE = Acute Physiology and Chronic Health Evaluation

Table 2. Indications for Percutaneous Dilatational Tracheostomy Among 228 Patients

Clinical Groupings	Before Protocol n (%)	During Protocol n (%)
Coma	85 (66)	54 (54)
Cerebrovascular accident	34 (40)	19 (19)
Brain injury	29 (34)	23 (23)
After cardiac arrest	11 (13)	5 (5)
Intracranial neoplasm	4 (5)	2 (2)
Other	7 (8)	5 (5)
Acute respiratory failure	15 (12)	13 (13)
Chronic respiratory failure	12 (9)	10 (10)
Heart failure	5 (4)	4 (4)
With end-stage liver failure	4 (3)	0
Quadriplegia	2 (2)	5 (5)
Upper airway obstruction	3 (2)	1 (1)
Post-operative respiratory failure	2 (2)	5 (5)
Neuromuscular failure	0 (0)	4 (4)
Chest trauma	0 (0)	4 (4)
Total	128 (100)	100 (100)

cases); they were excluded from the study, leaving 128 patients for study. These 128 patients (the pre-protocol group) formed a defining group, with a high percentage of inappropriate antibiotic use at the time of PDT, indicating that a change in our antibiotic policy was required. The protocol group included 102 patients studied prospectively over a 30-month period (July 1999 to January 2002). One of those patients was excluded because of anterior tracheal abscess, and one was excluded because of a previous tracheostomy problem, leaving 100 patients in the protocol group.

Table 1 shows the demographics and clinical characteristics, Table 2 shows the indications for PDT, and Table 3

Table 3. Timing of Percutaneous Dilatational Tracheostomies and Duration of Tracheostomies*

Period	Before Protocol† (d)	During Protocol‡ (d)
From ICU day 1 until PDT	6.6 ± 4.4	9.3 ± 6.4§
Total days in ICU after PDT	8.3 ± 10.5	9.7 ± 5.2
Total days on ward with tracheostomy in situ	22.5 ± 11.0	21.1 ± 11.3
Median days before weaning from artificial ventilation	2	2

*Excluding patients with permanent tracheostomies

†Before protocol n = 128 patients

‡During protocol n = 100 patients

ICU = intensive care unit

PDT = percutaneous dilatational tracheostomy

Values are mean ± SD

§p < 0.001

||Excluding chronically ill patients

shows the timing of PDT and duration of tracheostomy, for all the study participants, in both the pre-protocol and protocol groups.

Table 4 shows the microbiology results from blood cultures. Bacteremia immediately before tracheostomy was greater in the pre-protocol group (40/128, 31%) than in the protocol group (18/100, 18%), but the difference was not statistically significant (p = 0.09 by chi-square test). In the pre-protocol group, 15% (19/128) of the blood samples immediately prior to PDT grew coagulase-negative *Staphylococcus*, in contrast to only 4% (4/100) of the protocol group (p = 0.013 by chi-square test). In the pre-protocol group, blood cultures taken immediately before and after PDT showed that 6 patients grew an organism in the blood that had been absent immediately prior to PDT. The organisms found in those 6 patients were *Pseudomonas aeruginosa* (2 cases), coagulase-negative *Staphylococcus* (3 cases), and *Providentia* (1 case). In the 2 cases involving *Pseudomonas aeruginosa*, the same organism (same antibiogram) was grown from the lower respiratory tract. One of the patients with *Pseudomonas* was septic and had pneumonia prior to PDT. This patient developed septic shock within 12 hours of PDT and was growing an *Acinetobacter* species in addition to *Pseudomonas aeruginosa* in the lower respiratory tract.

Table 5 shows the bacterial pathogens grown from LRT samples, from both groups. The total numbers are similar, but the number of *Acinetobacter* species in the LRT showed an increase from 10% (6/58) in the pre-protocol group to 24% (12/49) in the protocol group.

Table 6 shows the incidence of infection complications (bacteremia with sepsis, pneumonia, and septic shock) during the perioperative period (immediately prior to PDT and up to 5 days after PDT). The total number of infection complications in the pre-protocol group (41/128, 32%)

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Table 4. Organisms Cultured from Blood Samples Drawn Immediately Before and After Percutaneous Dilatational Tracheostomy

Group	Species	Before Protocol*		During Protocol†	
		Before PDT	After PDT	Before PDT	After PDT
Gram-Positive	Coagulase-negative <i>Staphylococcus</i>	19	22	4	4
	<i>Staphylococcus aureus</i>	4	4	0	0
	Methicillin-resistant <i>Staphylococcus aureus</i>	1	1	1	1
	<i>Streptococcus pneumoniae</i>	1	1	0	0
	<i>Enterococcus faecalis</i>	2	2	2	2
Gram-Negative	<i>Klebsiella</i> species	3	2	1	1
	<i>Pseudomonas aeruginosa</i>	3	5	5	5
	<i>Acinetobacter</i> species	3	3	5	5
	<i>Serratia marcescens</i>	1	1	0	0
	<i>Stenotrophomonas maltophilia</i>	1	0	0	0
	<i>Providentia stuarti</i>	1	2	0	0
	<i>Enterobacter</i> species	1	1	0	0
Yeast	Non-albicans <i>Candida</i>	1	1	0	0
Total		41 (32%)	45 (35%)	18 (18%)	18 (18%)

*Before protocol n = 128 patients

†During protocol n = 100 patients

PDT = percutaneous dilatational tracheostomy

In the pre-protocol group, 6 patients (5%) developed positive blood cultures during PDT, and 2 had organisms cultured from the blood before but not after PDT.

Table 5. Pathogens Cultured from Lower Respiratory Tract Samples Taken Immediately Before and After Percutaneous Dilatational Tracheostomy

Group	Species	Before Protocol* n (%)	During Protocol† n (%)
Gram-Positive	Methicillin-resistant	3 (2)	4 (4)
	<i>Staphylococcus aureus</i>		
	<i>Staphylococcus aureus</i>	5 (4)	3 (3)
Gram-Negative	<i>Pseudomonas aeruginosa</i>	34 (27)	26 (26)
	<i>Serratia marcescens</i>	2 (2)	0
	<i>Klebsiella</i> species	4 (3)	4 (4)
	<i>Acinetobacter</i> species	6 (5)	12 (12)
	<i>Citrobacter</i> species	1 (1)	0
	<i>Morganella morganii</i>	2 (2)	0
	<i>Providentia</i> species	1 (1)	0
Yeast	<i>Candida albicans</i>	4 (3)	3 (3)
	Non-albicans <i>Candida</i>	6 (5)	4 (4)
Total		68 (55)	56 (56)

*Before protocol n = 128 patients

†During protocol n = 100 patients

was significantly greater than that in the protocol group (11/100, 11%) (p < 0.001). There were no cases of cellulitis in any of the patients.

In the pre-protocol group, LRT organisms in the 9 pneumonic patients at the time of PDT included 6 cases of

Table 6. Bacteremia, Colonization, and Infection in the Perioperative Period

	Before Protocol* n (%)	During Protocol† n (%)
Prior to Tracheostomy		
Bacteremia without sepsis	32 (25)	16 (16)
Bacteremia with sepsis	8 (6)	2 (2)
Lower airway colonization	63 (49)	56 (56)
Pneumonia	9 (7)	0 (0)
During the 5 Days Following Tracheostomy		
Bacteremia with sepsis	11 (10)	4 (4)
Septic shock	4 (3)	1 (1)
Pneumonia	9 (6)	4 (4)

*Before protocol n = 128 patients

†During protocol n = 100 patients

Pseudomonas aeruginosa and 1 of each of *Staphylococcus aureus*, *Citrobacter*, *Klebsiella*, and *Acinetobacter* species (1 patient had more than 1 organism). Six of these 9 pneumonic patients had positive blood cultures and all were clinically septic. Three patients grew the same organism from the blood and LRT simultaneously. Following PDT a further 9 patients developed clinical pneumonia by the third postoperative day. The LRT organisms in these 9 pneumonic post-PDT patients included 4 cases of *Pseudomonas aeruginosa* and 1 each of *Klebsiella*, *Acinetobacter*,

Table 7. Antibiotic Status in Relation to Infection and Colonization of the Lower Respiratory Tract in Patients Undergoing Percutaneous Dilatational Tracheostomy

Antibiotic Status	Before Protocol (n = 128)§			During Protocol (n = 100)		
	Pneumonia* n = 18 (%)	Bacteremia With Sepsis n = 19 (%)	LRT† Colonization n = 51 (%)	Pneumonia‡ n = 17 (%)	Bacteremia with Sepsis n = 6 (%)	LRT† Colonization n = 32 (%)
None	3 (17)	4 (21)	6 (12)	0	1 (17)	4 (13)
Inappropriate	12 (66)	13 (68)	27 (53)	2 (12)	2 (33)	3 (9)
Appropriate	3 (17)	2 (11)	18 (35)	15 (88)	3 (50)	25 (78)

*Pneumonia diagnosed at the time of tracheostomy or subsequently up to 5 days after tracheostomy
 †Lower respiratory tract (LRT) colonization with bacterial pathogens prior to tracheostomy
 ‡Pneumonia diagnosed at least 3 days prior to tracheostomy or subsequently up to 5 days after tracheostomy
 §Of 128 patients, 109 were receiving antibiotics and 19 were not

and *Serratia marcescens*. Two patients with clinical signs of pneumonia had no organisms cultured from the LRT, although organisms were grown from the blood. One patient had the same organism cultured from the blood and LRT simultaneously. Thirteen cases of resolving pneumonia were recorded in the protocol group at the time of PDT. The organisms involved in those pneumonias included 6 *Pseudomonas* species, 4 *Acinetobacter* species, 1 *Staphylococcus aureus*, 2 *Stenotrophomonas maltophilia*, and 1 *Enterococcus*. The LRT specimens from the 4 post-PDT pneumonias in the protocol group grew the following organisms: 2 *Acinetobacter* species, 1 *Pseudomonas aeruginosa*, and 1 *Stenotrophomonas maltophilia*.

The incidence of pre-PDT bacteremia with sepsis was 6% (8/128) in the pre-protocol group and 2% (2/100) in the protocol group. Organisms grown from the blood of 19 perioperative pre-protocol patients considered to be septic included 5 *Pseudomonas aeruginosa*, 4 *Klebsiella* species, 4 *Staphylococcus aureus*, 3 coagulase-negative *Staphylococcus*, and 1 of each of *Serratia* species, methicillin-resistant *Staphylococcus aureus*, and *Enterococcus faecalis*. Organisms grown from the blood of 6 perioperative protocol patients considered to be septic included 1 methicillin-resistant *Staphylococcus aureus*, 1 *Staphylococcus aureus*, 2 *Acinetobacter*, and 2 *Pseudomonas aeruginosa*. There were 4 patients in the pre-protocol group and 2 patients in the protocol group who had a systemic inflammatory response syndrome without positive cultures or obvious pneumonia.

In the pre-protocol group, 4 patients developed septic shock within 12 hours of PDT, 3 of whom had untreated nosocomial pneumonia at the time of PDT. One of those patients had a highly resistant *Acinetobacter* (sensitive to meropenem only) cultured from the LRT, but was receiving piperacillin/tazobactam for a *Pseudomonas* bacteremia with sepsis. Another one of those 4 patients had *Acinetobacter* species in the blood and *Klebsiella* cultured from the LTR and was receiving no antibiotics but responded to piperacillin/tazobactam commenced on the day of the PDT.

Another one of those 4 patients had *Pseudomonas aeruginosa* in the LRT and was receiving piperacillin/tazobactam, to which the *Pseudomonas* was resistant. Another one of those 4 patients grew no organisms from either the blood or the LRT and appeared to have suffered aspiration into the lungs and was receiving piperacillin/tazobactam. In the protocol group, only one patient clinically developed septic shock, but no organism was grown from the blood or LRT.

Assessment of antibiotic use in the pre-protocol group revealed that 85% (109/128) were receiving antibiotics at the time of PDT. In the pre-protocol group 16% (3/19) of the patients not on antibiotics, as compared to 14% (15/109) who were on antibiotics, were diagnosed with pneumonia at the time of PDT or subsequently for up to 5 days after PDT. However, of those 15 of 109 patients who developed pneumonia while receiving antibiotics, 34% (12/35) were receiving inappropriate empirical antibiotics for the organisms that were cultured from LRT, as compared to only 4% (3/74) of the patients who were considered to be receiving appropriate antibiotics ($p < 0.001$ by chi-square test). We assessed antibiotics appropriateness in the pre-protocol group in the light of all the microbiology data available for up to 1 week prior to PDT. The antibiotics considered were given for all indications; for example, some patients may have been incidentally receiving antibiotics for urinary tract infection, bacteremia without sepsis, or skin infection, in addition to the patients receiving empirical antibiotics for pneumonia and bacteremia with sepsis. Table 7 shows the presence or absence and appropriateness of the antibiotics strictly in regard to the incidence of pneumonia, bacteremia with sepsis, and organisms responsible for LRT colonization at the time of PDT and for 5 post-operative days.

Table 7 shows antibiotic use and appropriateness in regard to the incidence of pneumonia, bacteremia with sepsis, and organisms responsible for LRT colonization. Under the protocol all patients considered to be suffering from pneumonia had the pneumonia treated with appro-

Table 8. Individual Serious Early Noninfective Complications After Percutaneous Dilatational Tracheostomy

Complication	Before Protocol* n (%)	During Protocol† n (%)
Bleeding	2 (2)	2 (2)
Pneumothorax	2 (2)	1 (1)
Failed tracheotomy	3 (2)	1 (1)

*Before protocol n = 128 patients
†During protocol n = 100 patients

appropriate antibiotics before undergoing PDT, so virtually no protocol patients with active pneumonia received inappropriate or no antibiotics. Thirteen cases of resolving pneumonia were recorded among the protocol group at the time of PDT. However, of the 4 protocol group patients who developed pneumonia in the 5 days following PDT, 2 had inappropriate antibiotics prescribed initially. Piperacillin/tazobactam was our first-line antibiotic for nosocomial pneumonia and was selected based on research on ICU isolates in our laboratories. Piperacillin/tazobactam was administered in 56% (72/128) of pre-protocol and 44% (44/100) of protocol patients at the time of PDT. Only 5% (6/128) of pre-protocol patients received meropenem, compared to 23% (23/100) of protocol patients ($p < 0.001$ by chi-square test). Aminoglycoside use was also frequent but similar: 23% (30/128) in the pre-protocol group versus 27% (27/100) in the protocol group.

Overall ICU and hospital mortalities were 25% (57/228) and 43% (97/228), respectively, but no patient died as a result of PDT. Pre-protocol and protocol hospital mortality was not significantly different (48% [61/128] vs 36% [36/100], $p = 0.10$ by chi-square test). The mortality of the 35 patients who acquired pneumonia during the perioperative period was not significantly different from the 194 patients who did not suffer pneumonia (40% [14/35] vs 33% [63/193]).

Serious noninfection complications were found to be similar in the 2 groups immediately following PDT (Table 8). Segmental lung collapse was the commonest nonserious complication. The segmental lung collapse rate following PDT was 13% (17/128) in the pre-protocol group and 4% (4/100) in the protocol group ($p = 0.030$ by chi-square test).

Discussion

The lower infection rate in the protocol compared to the pre-protocol group was considered to be related mainly to patients with pneumonia, bacteremia with sepsis, and colonization of the LRT with pathogens receiving a greater degree of appropriate antibiotic cover in the perioperative period (see Table 7) (protocol group 86% [43/50] vs pre-

protocol group 31% [23/75], $p < 0.001$). However, the experimental methods in this study suffer from many limitations. We compared 2 groups of patients separated by a considerable time interval, and differences other than the antibiotic protocol could have contributed to the results. These differences included age and sex, disease categories, changes in infection patterns, changes in intravascular catheter management, and changes in timing and model of PDT set used to perform tracheostomy, as discussed below.

The entry characteristics of the 2 groups were similar (see Table 1) with regard to demographics, severity of illness, comorbidities, and clinical classification for performance of PDT, except for a difference in age and a preponderance of male patients in the pre-protocol group (pre-protocol 82% vs protocol 63%, $p = 0.002$ by chi-square test). There were also significant differences in the interval between ICU admission and tracheostomy (pre-protocol 6.6 ± 4.4 days vs protocol 9.3 ± 6.4 days, $p < 0.001$). The reason for the longer interval between ICU admission and tracheostomy may relate to an increasing reluctance on the part of some referring physicians and surgeons to allow early tracheostomy. Patients in the protocol group may have been given more chances to wean off mechanical ventilation and to undergo a trial of extubation before resorting to tracheostomy. The delay imposed by our protocol may also have contributed. However, there was no significant difference between the groups with regard to the interval between PDT and discharge or the interval between PDT and weaning off mechanical ventilation. Overall ICU and hospital mortalities were 25% (57/228) and 43% (97/228), respectively, but no patient died as a result of PDT. Hospital mortality in the 2 groups was not significantly different (pre-protocol 48% [61/128] vs protocol 36% [36/100], $p = 0.10$).

Nosocomial pneumonias are not easily diagnosed in the ICU. We used the CPIS, the overall accuracy of which for diagnosing nosocomial pneumonia is 79%.²⁴ The specificity of the CPIS, when combined with logarithmic concentration of the predominant organism, is reported to be as high as 95%.²⁴ We only diagnosed pneumonia if the patient had a CPIS > 6 together with a semi-quantitative assessment of the organism numbers. Sensitivity with the CPIS is reported to be 72%.²⁴ Our overall perioperative pneumonia rate of 15% (35/228, including 18 pre-protocol patients, and 17 protocol patients) was much less than that described by Elatrous et al (86% [13/15])⁹ in their study of ventilator-associated pneumonia and tracheostomy, and even of their overall ICU rate of 38% (28/73). In our study there were no cases of cellulitis, which can be a serious tracheostomy complication.⁵

Coagulase-negative *Staphylococcus* was present in 15% (19/128) of the pre-protocol group immediately prior to PDT, compared to 4% (4/100) of the protocol group ($p =$

0.013 by chi-square test). Intravascular lines have been shown to be the commonest sources of infection with coagulase-negative *Staphylococcus* in the pediatric ICU, accounting for 41.2% of all episodes.³⁰ The considerable reduction in coagulase-negative *Staphylococcus* infections during the protocol period could be explained by the tightening up of our management of intravascular lines. Our incidence of positive blood cultures among the entire 228 study patients was 25%, which was considerably higher than that described by Teoh et al,³¹ which was 6.6% of positive blood cultures in general ICU patients. On the other hand, blood contamination during the procedure was low: only 6 new bacteremias (3%) occurred (among 228 patients) immediately following PDT, which was less than the incidence of 9.5% previously reported.³¹ In regard to changes in antibiotic prescribing, there was a significant increase in our use of meropenem, which mirrored our increase in isolates of *Acinetobacter* species in our ICU during the protocol period (pre-protocol group 7% [9/128] vs protocol group 17% [17/100], $p < 0.001$).

We found Ciaglia's technique easy and rapid to perform, especially with the latest single-dilator modification, the Blue Rhino set. We believe this set is an advance on the older multiple-dilator sets (7 dilatations compared to only 1), which makes the procedure faster and reduces trauma, tissue contamination, and bleeding. Our serious noninfection complication rate (see Table 8) of 4.4% (11/228) was in keeping with other studies^{3,4} and was similar between our 2 groups. The segmental lung collapse rate following PDT was 13% (17/128) in the pre-protocol group and 4% (4/100) in the protocol group ($p = 0.012$). The reason for the lower incidence of segmental lung collapse in the protocol group may relate to less bleeding with the single-dilator technique. We did not have the oxygenation problems described in the study by Westphal et al;¹⁰ there was no case in which a loss of the airway occurred during the procedure. No procedure had to be abandoned because of technical inability.

Conclusions

Our simple protocol for the use of antibiotics prior to PDT in ICU patients may have been effective in reducing perioperative bacterial infections.

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Appendix

Clinical Pulmonary Infection Scoring System for Diagnosing Nosocomial Pneumonia

1. Temperature (°C)	0 point
≥ 36 and ≤ 38.4	
≥ 38.5 and ≤ 38.9	1 point
≥ 39 or ≤ 36.0	2 points
2. Blood Leukocytes (per mL)	
≥ 4,000 and < 11,000	0 point
< 4,000 or ≥ 11,000	1 point
< 4,000 or ≥ 11,000 + band forms > 500	2 points
3. Tracheal Suctionings Required in a 24-h Period (<i>n</i>)	
< 14 of tracheal secretions	0 point
≥ 14 of mucoid tracheal secretions	1 point
≥ 14 of purulent tracheal secretions	2 points
4. Oxygenation: P _{aO₂} /F _{I_{O₂}} (mm Hg)	
> 240 or acute respiratory distress syndrome	0 point
≤ 240 and no evidence of acute respiratory distress syndrome	2 points
5. Pulmonary Radiograph	
No infiltrate	0 point
Diffuse infiltrates	1 point
Localized infiltrates	2 points
6. Culture of Tracheal Aspirate (semi-quantitative scale: 0, 1, 2, or 3+)	
Pathogenic bacteria cultured ≤ 1 + or no growth	0 point
Pathogenic bacteria cultured > 1 +	1 point
Pathogenic bacteria cultured > 1 + same organism seen on Gram stain	2 points

Clinical pulmonary infection score (CPIS) > 6 = nosocomial pneumonia

P_{aO₂}/F_{I_{O₂}} = ratio of arterial partial pressure of oxygen to fraction of inspired oxygen (Adapted from Reference 25.)
