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Original Article

Impact of Antibiotic Therapy during Bedside Percutaneous Tracheotomy procedure in an Intensive Care

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Introduction: Percutaneous bedside tracheostomy (PBT) is a frequently done procedure in the intensive care unit (ICU). The rate of infectious complications and efficacy of perioperative therapy in reducing infections after PBT is currently unknown.
Methods: All demographic, clinical and microbiologic data was retrospectively collected from 110 cases of PBT performed in our ICU from 2006 to 2012. Of these patients, 82 patients received perioperative antibiotic therapy (Group 1, "antibiotic group") and 28 did not receive antibiotics (Group 2, "Non antibiotic group").
Results: Patients who received antibiotic therapy had a lower incidence of new ventilator associated pneumonia (VAP) episodes [18% vs. 50 %, $p = 0.001$ (0.23, 0.87-0.13)]. There were no differences in the incidence of bacteremia or line sepsis. Overall Gram negative, Gram positive and fungal flora was similar in both groups before and after PBT.
Conclusions: Our findings highlight the importance of conducting a prospective randomized control trial to better understand the role of antibiotic prophylaxis in PBT.

Key words: *bacteremia, infectious complications, line sepsis, new VAP episode, percutaneous bedside tracheostomy*

Introduction

Over the past two decades percutaneous bedside tracheostomy (PBT) has become a frequent and popular procedure in the critically ill population.[1] As a conservative open surgical procedure, the PBT technique has been utilized for the same clinical indications as the open surgical technique (OST), including protection of the larynx and upper airway, and for prolonged mechanical ventilation.[1,2] Despite the relative cost reduction of PBT, surgical blood loss and the rate of infectious complications (wound infections and new ventilator-associated pneumonia-VAP) after PBT are supposed to be similar to the OST.[2]

PBT is a clean-contaminated procedure, and the duration of the procedure 15-20 minutes depending of the physician's procedural skills.[2,3] Importantly, PBT is typically performed in a contaminated intensive care unit (ICU) environment, whereas OST is performed in a clean operation room.

The exact rate of infectious complications after PBT is unknown. Some studies have demonstrated

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a relatively high incidence of ventilator-associated pneumonia (VAP) (up to 25%) in the early post-tracheotomy period.[3-5] Other authors however have argued that PBT technique results in a decreased incidence of VAP compared with OST.[6] Similarly, the incidence of secondary bacteremia associated with PBT in critically ill patients was shown to range from 10 to 30%.[7,8]

Currently there have been no definitive recommendations for prophylactic antibiotic therapy before PBT in the ICU. The aim of this study was to review the impact of antibacterial therapy on rate of infectious complications (new bacteremia, line sepsis and VAP) after bedside PBT procedures for patients in the general ICU at our institution.

Patients and Methods

The Human Research and Ethics Committee at Soroka Medical Center in Beer-Sheva, Israel approved this study (RN-0028-13-SOR). This is a retrospective observational study and no patient's consent was needed. We retrospectively collected clinical data from all cases of PBT performed in the general ICU at Soroka Medical Center from January 2006 through June 2012. Soroka Medical Center is a tertiary care facility with 1,100 inpatient beds, including 12 general ICU beds. All clinical data was extracted from the Register Information System and electronic reports.

Inclusion criteria

All patients who underwent planned PBT which performed in the general ICU at Soroka Medical Center from January 2006 through June 2012.

Exclusion criteria

Patients who underwent an emergency/urgent PBT with a disrupted aseptic technique were excluded from the study. Patients who were ventilated and developed VAP before PBT procedure were excluded from the study. Also, patients who were converted from PBT technique to OST due to failure of insertion were excluded from the study.

Variables and measures

Demographic data, including the ICU admission diagnosis, APACHE-II score (acute physiology and chronic health evaluation II score), cardiovascular parameters (heart rate and systemic blood pressure), respiratory parameters (respiratory rate, PaO2/FiO2, PaCO2), body temperature, rate of weaning from mechanical ventilation, and in-hospital mortality was reviewed from patients' records. White blood cell counts and microbiologic culture results of sputum, blood and central venous catheter (CVC) tips during the ICU stay before PBT performance and 72 hours after the PBT procedure were also included.

Demographic data and microbiological cultures were analyzed during the ICU stay before PBT performance and 72 hours after the PBT procedure.

Definitions

Antibiotic group (Group 1) was defined as patients in whom the PBT procedure was performed in the ICU, with antibiotics administered 72 hours perioperative procedure (PBT). Antibiotic therapy was initiated during the ICU stay before the PBT performance for some other reasons (previous infectious events).

Non antibiotic group (Group 2) was defined as patients whom in whom the PBT procedure was performed in the ICU without antibiotics administered 72 hours prior to and during the procedure. New bacteremia, new catheter-related infection, low airway colonization and VAP during the 72 hours in relation to PBT procedure were considered infectious complications. New bacteremia, catheter-related infections were defined according to diagnostic criteria of Guidelines for the Prevention of Intravascular Catheter-related Infections of Centers for Disease Control (CDC).[9-11] Low airway colonization was defined as low airway bacterial colonization by different microbiological flora.[12] The diagnostic criteria of new VAP episode were according to the international surveillance guidelines of Centers for Disease Control, Ventilator-Associated Events (VAE) Surveillance Algorithm including clinical data of worsening oxygenation, temperature, purulent respiratory secretions and positive culture of endotracheal aspirate > 10^5 CFU/ml or equivalent semi-quantitative result.[13-17] The quality of sputum was evaluated by using bronchoalveolar lavage (BAL), semi-quantitative cultures by bronchoscopy.[11]

ICU protocol for percutaneous bedside tracheostomy

All ICU procedures were performed according to an institutional protocol. Patients were consented

to the procedure, and the clinical staff reviewed the indication for PBT. Every patient was examined by an intensive care physician before starting the procedure for the presence of any of the following clinical contraindications of PBT: anatomical neck limitations, significant coagulopathy, morbid obesity, pulsatile artery over the surgical area, and inability to identify the cricoid cartilage. If any of these contraindications to PBT were present, an otolaryngology team in the operating room performed the tracheotomy.

Our ICU team consists of one intensive care specialist with at least 2 years of procedural experience, one surgical assistant (resident or ICU fellow), and a registered nurse. The protocol includes a sterile standardized set for PBT that was checked prior to starting the procedure. The procedure was done via an aseptic technique, in which a sterile dressing, coverage, and skin preparation with 2% chlorhexidine in 70% isopropyl alcohol was applied.

All PBT procedures were done using Seldinger technique with serial dilatation.

There were no clinically significant deoxygentaion, bleeding, surgical site infection during and after the procedure.

All PBT procedures were performed under adequate sedation and muscle relaxation, and with the administration of 100% oxygen. Patients' hemodynamics was continuously monitored for the duration of the procedure. The duration of each procedure in our unit was about 20 minutes, which correlates well with previously published data.[3] A chest X-ray was routinely done after procedure. An otolaryngologist was immediately available in the event of potential complications, and this was confirmed just prior to starting the procedure.

Statistical analysis

For categorical variables, proportions were compared using Fisher's Exact Test or Chi Square as appropriate. Continuous variables were analyzed with a Student's t-test or the Wilcoxon Rank Sum Test, depending on the validity of the normality assumption. A two-tailed *p*-value of < 0.05 was considered to be significant. All analysis was performed using SPSS version 17 (SPSS, Chicago, IL).

Results

110 PBTs were done from 2006 to 2012. There were 82 patients who treated by antibiotic (Group 1) and 28 patients with no antibiotic therapy (Group 2) identified. There were no clinically significant deoxygentaion, bleeding, surgical site infection during and after the procedure (PBT).

No differences were found in age, gender, or admission diagnoses between the two study groups (see Table 1). The length of ICU stay and in hospital mortality rate was similar between both study groups.

Patients in group 2 (no perioperative antibiotic treatment) had a higher incidence of new VAP episodes compared to group 1 ($p = 0.001$, Table 2). There were no statistically significant differences in bloodstream bacteremia or line sepsis between the study groups (Table 2). The total length of antibacterial therapy during the ICU stay was significantly longer in patients in group 1 (12.62 ± 5.717 vs. 7.18 ± 4.91 days in group 2, $p < 0.0001$, Table 2).

There were no differences in the sputum growth of highly virulent pathogens including *Pseudomonas aeruginosa*, *Acinetobacter spp*, *Klebsiella spp* and *Staphylococcus aureus* (methicillin sensible and resistant) before and after PBT between both study groups (*p* Group 1 vs. Group 2 - NS). Moreover, overall Gram negative, Gram positive and fungal flora was similar in both groups before and after PBT. The gram-negative microorganisms in patients in group 1 demonstrated a decreased susceptibility to meropenem ($p < 0.018$), Piperacillin/Tazobactam ($p < 0.0001$), Ceftazidime ($p < 0.015$), Ciprofloxacin ($p < 0.001$), Gentamicin ($p < 0.0001$) and Amoxicillin/clavulanic acid (0.025) after PBT, but no differences in susceptibility for gram-positive microorganisms. In group 2, there were no differences in sensitivity patterns for Gram-negative or Gram-positive flora after the procedure (Table 3). There was no significant difference of antibiotic susceptibilities between group 1 and group 2, either before or after PBT.

Discussion

In this study, we examined the rate of infectious complications associated with PBT procedure with, and without perioperative antibiotic administration. Our results demonstrated that number of VAP after PBT is a relatively higher despite aseptic technique in group without antibiotic administration. The incidence of VAP was significantly decreased when antibiotics were administered during the perioperative period.

In prior studies, antibiotic prophylaxis before in-

Table 1. Demographic data and clinical outcome end points for study groups

	Group 1[a] (n = 82)	Group 2[a] (n = 28)	Total (n = 110)	*p* value OR (95% CI)*
Age (mean ± SD)	49.13 ± 19.824	56.89 ± 18.725	51.2 ± 19.759	0.073
Gender [male/all (%)]	60 (73.2%)	21 (75%)	81 (74.5%)	0.85
Diagnosis on admission				
Peritonitis	20 (18.2%)	5 (17.8%)	25 (22.7%)	0.478
Pneumonia	4 (3.6%)	6 (21.4%)	10 (9.1%)	0.008, 0.19 (0.01-0.7)
Trauma	47 (42.7%)	12 (42.8%)	59 (53.6%)	0.185
Other[b]	11 (13.4%)	5 (17.8%)	16 (10.9%)	0.55
Length of ICU stay (days, mean ± SD)	32.5 ± 22.933	26.64 ± 13.262	31.01 ± 20.999	0.204
APACHE score (units, mean ± SD)	24.61 ± 4.817	24.64 ± 5.424	24.62 ± 4.953	0.976
Length of mechanical ventilation (days, mean ± SD)[c]	17.9 ± 5.2	16.8 ± 7.4	17.1 ± 6.3	0.3
Weaning success[d] (%)	44 (53.76%)	15 (53.6%)	59 (53.6%)	0.5
Crude mortality rate (%)	11 (13.4%)	2 (7.14%)	13 (11.8%)	0.3

[a]Group 1: Patients who received antibacterial therapy (antibiotic group) during the perioperative period. Group 2: Patients who did not receive antibiotic therapy (Non antibiotic group) during the perioperative period.
[b]Other diagnoses on admission to the ICU included acute pancreatitis, coma, stroke, brain infarcts, multiple sclerosis, diabetic ketoacidosis, aortic abdominal aneurysm repair, acute subarachnoid hemorrhage, and organophosphate poisoning.
[c]Length of mechanical ventilation during the ICU stay.
[d]Percent of patients who successfully weaned from mechanical ventilation during the ICU stay.
**p* value < 0.05 was defined as statistically significant.

vasive procedures such as insertion of drainage tubes, central intravenous catheters, and urinary catheters failed to decrease the rate of infectious complications.[18] Although PBT is considered a minor surgical procedure the procedure necessitates that the upper respiratory tissues are disrupted and manipulated. As such, the efficacy of antibiotic prophylaxis in reducing the incidence of infectious complications is unknown.

Although the PBT procedure is a commonly performed, routine procedure in the ICU, some authors have suggested that it might be associated with new episodes of bacteremia, VAP and line sepsis.[7,19] The epidemiology of bacteremia and new VAP are likely related to previous colonization of the lower respiratory tract[3,8,20,21] that may be present in up to 90% of the ICU population. Even more so, the majority of tracheal cultures might reveal the presence of virulent and multi-drug resistant Gram-negative bacilli including *Pseudomonas aeruginosa*, *Acinetobacter species*, as well as Gram-positive cocci that mostly include *Staphylococcus aureus* [methicillin sensitive staphylococus aureus/methicillin resistant staphyococcus aureu (MSSA/MRSA)].[3,8,21,22] In our study both Gram-negative bacilli and Gram-positive cocci pathogens were present in tracheal cultures critically ill patients with new VAP after PBT procedure (Table 3). When compared of antibiotic susceptibilities, either before or after PBT, there was no significant difference in between group 1 and group 2 (including the lower sensitivity of meropenem in group 2 remained unchanged before and after PBT). It is a crucial to carefully manage antibiotic therapy in order to avoid decrease sensitivity and MDR strains growth. The total rate of new VAP in our study was 26%, which was similar to previously published studies (15-38%).[8,20]

The new VAP episodes were found to be significantly higher in patients with no antibiotic coverage before, during, or after the PBT procedure (perioperative period). This suggests that antibiotics may play a critical role in preventing VAP. A prior study[8] demonstrated that appropriate antibiotic prophylaxis administration immediately prior to PBT was highly effective in reducing infectious complications. In their study, the overall rate of infectious complications after PBT was decreased from 32% to 11% when an-

Table 2. Clinical data of new infectious events during the perioperative period (during the ICU stay before PBT performance and 72 hours after the PBT procedure) (A); New VAP episode 72 hours after the PBT procedure and the total length of antibacterial therapy during the ICU stay of both study groups (B)

A. New infectious events during the perioperative period

Infections by group[a]	Before PBT	After PBT	*p* value OR (95% CI) *
Bacteremia			
Group 1	25/82 (30.5%)	21/82 (25.6%)	0.488
Group 2	6/28 (21.9%)	11/28 (39.3%)	0.149
Low airway colonization			
Group 1	67/82 (82.7%)	77/82 (93.9%)	0.012, 0.29 (0.1-0.84)
Group 2	24/28 (85.7%)	23/28 (82.1%)	0.718
Catheter-related infection			
Group 1	8/82 (9.8%)	10/82 (12%)	0.39
Group 2	5/28 (17.9%)	4/28 (14.3%)	0.718

B. New VAP episode and total length of antibacterial therapy

	Group 1[a]	Group 2[a]	Total	*p* value OR (95% CI)
New VAP events (%)	15/82 (18.2%)	14/28 (50%)	29/110 (26.4%)	0.001, 0.23 (0.87-0.13)
Length of antibiotic therapy (days)[b]	12.62 ± 5.717	7.18 ± 4.91	11.24 ± 5.99	0.0001, 7.2 (14.2-4.63)

[a]Group 1: Patients who received antibacterial therapy (Antibiotic group) during the perioperative period. Group 2: Patients who did not receive antibiotic therapy (Non antibiotic group) during the perioperative period.
[b]Length of antibiotic therapy during the ICU stay reflects the total number of days of antibacterial therapy during the ICU stay in both study groups.

tibiotics were prophylactically administered.

Our retrospective study highlighted the importance of antibiotic therapy during the perioperative timeframe, but it is important to note that we did not administer the same antibacterial prophylaxis for all patients. The patients received antibiotic treatment based on prior infections, positive culture sensitivities, or empirically broad antibacterial coverage.

The most recent international guidelines of the VAP Surveillance Definition Working Group states that chest imaging is unnecessary for diagnosing new VAP.[23] However, that statement was not intended for clinical practice,[23] and the bedside chest x-ray remains an indispensible diagnostic tool for monitoring critically ill patients in the ICU.[24] In our study we did not use radiological findings for diagnosing a new VAP.

Bacteremia after PBT has been well described in the literature, with an overall percent risk that ranges from 5.3 to 25%.[8,19,25] In our study, no statistical significant differences in new bacteremia events were shown. However, a detailed analysis of both study groups demonstrated a trend toward a higher percent of new bacteremia in patients who did not receive antibiotics after PBT (21.9% versus 39.3%). Our failure to reach statistical significance might be explained by our small sample size.

Our study had a number of limitations. As a retrospective study, we demonstrated that antibiotic therapy during PBT resulted in significant fewer VAP episodes. However, our study cannot confirm which antibiotics, or the appropriate time or duration of therapy is most suitable and effective before PBT. Our retrospective study design carry with it two important biases.

One a surveillance bias, it is possible that the clinicians order more test for those did not receive peri-operative antibiotics, and subsequently more complication were disclosed in this group and an indication bias where antibiotics were missed, which would be associated with imperfect aseptic procedure, patients condition and operator experience.

These are important questions that need to be addressed because currently, inappropriate use of antibiotics has greatly contributed to multidrug resistant bacteria strains in the ICU.

Table 3. Antimicrobiological sensitivity of Gram-negative and Gram-positive microorganisms (sputum cultures before and after bedside tracheostomy performance during the ICU stay).

Antibiotic Treatment	Before PBT	After PBT	*p* value* OR (95% CI)
Group 1[a] (n = 82)			
Gram negative microorganisms			
Meropenem	53/53 (100%)	54/60 (90%)	< 0.018
Pip/tazo	35/41 (84.5%)	38/67 (56.7%)	< 0.015, 3.75 (1.25-12.2)
Ceftazidime	30/35 (85.7%)	32/52 (61.5%)	< 0.015, 3.75 (1.25-12.2)
Cefuroxime	23/27 (84.8%)	23/30 (76.63%)	0.419
Ciproxin	34/36 (94.4%)	36/45 (80%)	< 0.001, 8.9 (1.9-41.4)
Gentamicin	33/38 (86.8%)	34/62 (54.8%)	< 0.0001, 5.4 (1.8-15.7)
Amp/Clav	18/18 (100%)	19/25 (76%)	0.025
Amikacin	42/45 (92.3%)	45/66 (68.2)	0.06
Tobramycin	21/23 (91.3%)	21/25 (84%)	0.729
Colistin	8/8 (100%)	8/12 (66.7%)	0.067
Amox/clav	3/3 (100%)	3/3 (100%)	0.79
Ampicillin	3/4 (75%)	4/11 (36.4%)	0.20
TMP/SMX	3/3 (100%)	3/5 (60%)	0.712
Gram positive microorganisms			
Oxacillin	5/5 (100%)	5/5 (100%)	0.1
Clindamycin	5/5 (100%)	5/5 (100%)	0.1
Rifampicin	5/5 (100%)	5/5 (100%)	0.1
Vancomycin	12/12 (100%)	12/12 (100%)	0.1
Group 2[a] (n = 28)			
Gram negative microorganism			
Meropenem	7/10 (70%)	8/14 (57.1%)	0.53
Pip/tazo	8/9 (88.9%)	8/16 (50%)	0.056
Ceftazidime	4/6 (66.7%)	5/ 10 (50%)	0.528
Cefuroxime	2/2 (100%)	2/2 (100%)	0.1
Ciproxin	6/8 (75%)	6/10 (60%)	0.51
Gentamicin	7/8 (87.5%)	7/12 (78.5%)	0.361
Amp/Clav	2/2 (100%)	2/4 (50%)	0.263
Amikacin	8/9 (88.9%)	8/14 (57.1%)	0.114
Tobramycin	3/3 (100%)	3/3 (100%)	0.1
Colistin	2/2 (100%)	2/3 (66.7%)	0.1
Gram positive microorganisms			
Oxacillin	5/5 (100%)	5/5 (100%)	0.1
Vancomycin	6/6 (100%)	6.6 (100%)	0.1

[a]Group 1: Patients who received antibacterial therapy (Antibiotic group) during the perioperative period. Group 2: Patients who did not receive antibiotic therapy (Non antibiotic group) during the perioperative period.
Pip/tazo = piperacillin/tazobactam, Amp/clav = ampicillin/clavulanic acid, TMP/SMX = Trimethoprim-sulfamethoxazole.
**p* value < 0.05 was defined as statistically significant.

Conclusion

In conclusion, VAP after PBT in the ICU appears to be an important infectious complication, even when a strict aseptic technique is employed. In our study, it might be considered that the incidence of

VAP episodes was diminished by the administration of antibiotics during the PBT procedure. Our findings stress the importance of conducting a prospective randomized trial to further study the role of antibiotic prophylaxis in PBT.

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