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Original Article

Effects of Antibiotics Administration on the Incidence of Wound Infection in Percutaneous Dilatational Tracheostomy

Hideharu Hagiya[a,b]*, Hiromichi Naito[b], Shingo Hagioka[b], Shuji Okahara[b,c], Naoki Morimoto[b], Nobuchika Kusano[d], and Fumio Otsuka[a]

[a]Department of General Medicine, Okayama University Graduate School of Medicine, Dentistry and Pharmaceutical Sciences, Departments of [c]Anesthesiology and Resuscitology, and [d]Infectious Disease, Okayama University Hospital, Okayama 700–8558, Japan, [b]Emergency Unit and Critical Care Center, Tsuyama Central Hospital, Tsuyama, Okayama 708–0841, Japan

The effect of antibiotics during the perioperative period of percutaneous dilatational tracheostomy (PDT) is still controversial. A total of 297 patients who underwent the PDT procedure were divided into 2 groups: those administered antibiotics perioperatively and those not administered antibiotics. Wound infections were noted in 7 cases (incidence rate, 2.36%) and no death was recorded. Of the 69 patients without antibiotics, 5 developed wound infections (incidence rate, 7.25%), while only 2 of the 228 patients with antibiotics developed wound infections (incidence rate, 0.88%) ($p = 0.002$; risk ratio, 8.82; 95% confidence interval, 1.67–46.6). Of the 7 cases of wound infection, 5 cases occurred during the early period after PDT (within 7 days). Collectively, the present results suggest that prophylactic administration of antibiotics may prevent the incidence of PDT-induced wound infection, especially in the early phase after the PDT procedures. The need for antibiotics in PDT should be reconsidered.

Key words: airway management, critically ill patient, percutaneous dilatational tracheostomy, and surgical site infection

Tracheostomy is a fundamental practice for long-term airway management of critically ill patients. Recently, percutaneous dilatational tracheostomy (PDT) has been widely used and is preferred to surgical tracheostomy (ST), since it is easier to perform and requires less time [1–5], yields fewer complications (*e.g.*, hemorrhage, pneumothorax, and tracheal stenosis) [6, 7] including infection [8–11], produces cosmetically better results [12], is more cost-effective [3, 7, 13], and results in a lower mortality rate [1].

Wound infection related to PDT can be lethal or may require long-term treatment for critically ill patients. However, antibiotics are generally not administered during the perioperative period of the tracheostomy because at present there is scant evidence of their effectiveness [12]. We investigated whether administration of antibiotics during the perioperative period of PDT would reduce the incidence of wound infection.

Materials and Methods

Study subjects. This single-center retrospective study was conducted in the open-type combined medical/surgical intensive care unit (ICU) of Tsuyama Central Hospital, Okayama, Japan. The present study (No. 167) was approved by the Institutional Review Board (IRB) of Tsuyama Central Hospital.

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*Corresponding author. Phone:+81–86–235–7342; Fax:+81–86–235–7345
E-mail:e_dai_for_all@hotmail.com (H. Hagiya)

PDT procedure and administration of antibiotics. The study period was between January 1st, 2004 and March 31st, 2011. The participants were critically ill adult patients (older than 20 years of age) who were admitted to our ICU for any reason and judged by at least 2 intensivists to be in need of tracheostomy. Among the patients, those with contraindications for PDT such as anatomical abnormality were excluded. PDT was performed according to the Ciaglia Blue Rhino technique (NEO PERC, Covidien, Japan) with bronchoscope assistance (Fig. 1).

Surgical site infection (SSI) is generally diagnosed by inflammatory changes such as tenderness, swelling, or redness around the surgical site within 30 days after a surgical procedure [14]. In this study, we defined a wound infection after PDT as infection-induced inflammatory changes at the tracheostomy site within 30 days after PDT, accompanied by systemic fever, pustular discharge, redness or tenderness.

The patients' medical records were checked retrospectively to determine whether any antibiotics were administered on the day of PDT. Patients who received and those who did not receive antibiotics were classified into an Abx (antibiotics) group and Non-Abx (non-antibiotics) group, respectively. We investigated wound infection (rate), length of ICU stay after tracheostomy, overall ICU stay, period of hospital stay after tracheostomy, and number of deaths related to wound infection. The early period after PDT was defined as the first 7 days after the procedure.

Statistical analysis. Data were analyzed using SPSS version 17.0. Variables were compared with the t test and χ^2 test with Yates' continuity correction. The level of significance was set at $p < 0.05$.

Results

PDT was performed in 385 patients. Eighty-eight patients were excluded since they died due to primary diseases within 30 days after PDT. There was no death caused by PDT-related complications. Thus the data for 297 cases were included in the final analysis (Fig. 2).

The major underlying disease on admission to the ICU was neurological disorders, followed by trauma and respiratory failure (Table 1). Overall, the Non-Abx group consisted of 69 patients (34 men and 35 women; mean age, 70.4 years; age range, 29 to 91 years) and the Abx group consisted of 228 patients (160 men and 68 women; mean age, 70.5 years; age range, 32 to 98 years). The percentage of males was significantly greater in the Abx-group. Serum albumin and C-reactive protein (CRP) levels before PDT, the timing of PDT after admission to the hospital, and the duration of endotracheal intubation prior to tracheos-

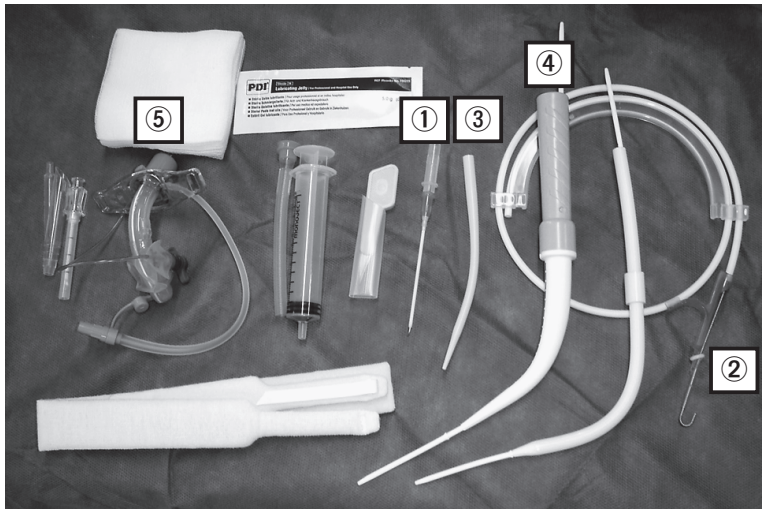

Fig. 1 The percutaneous dilatational tracheostomy (PDT) kit used in this study. 1) Puncture needle; 2) Guide wire; 3) 1st dilator; 4) 2nd dilator; and 5) Cuffed tracheostomy tube (NEO PERC, Tyco Healthcare, Tokyo, Japan). The items are numbered in their order of use during the procedure.

tomy were not significantly different between the 2 groups. Among patients with neurological disorders, males outnumbered females. Moreover, the serum albumin and the CRP level of the Abx group were significantly different compared to those of the Non-Abx group. Among patients with trauma, the CRP level was higher in the Abx group. A summary of the baseline characteristics of the patients in the Abx, Non-Abx and various subgroups is shown in Table 2.

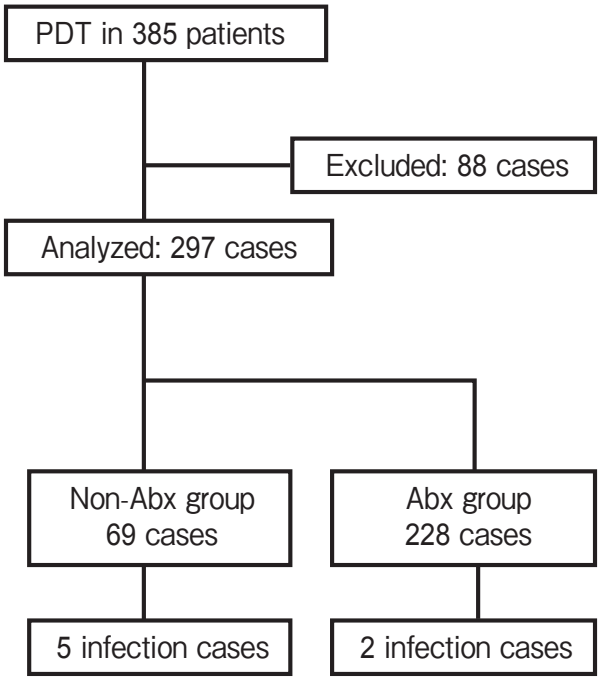

Fig. 2 Flow diagram of the present study. Among the 88 excluded cases, there was no case with PDT-related complications. PDT: percutaneous dilatational tracheostomy; Abx group: antibiotics group; and Non-Abx group: non-antibiotics group.

Various antibiotics, such as penicillins (used in 25.5% of cases; ampicillin, ampicillin/sulbactam, piperacillin, and piperacillin/tazobactam), cephems (22.9%; cefazolin, cefotiam, cefmetazole, ceftriaxone, cefotaxim, ceftazidime, cefepime, and cefoperazon/sulbactam), anti-MRSA drugs (14.7%; vancomycin, teicoplanin, arbekacin, and linezolid) were administered perioperatively to treat primary infections in each patient.

The main results are shown in Fig. 3. Overall, wound infection was noted in 7 patients (Fig. 3A). The total incidence rate of wound infection was calculated as 2.36%. Of the 69 patients in the Non-Abx group, 5 developed wound infection (incidence rate, 7.25%), while 2 of the 228 patients in the Abx group developed wound infection (incidence rate, 0.88%) ($p = 0.002$; risk ratio, 8.82; 95% confidence interval (C.I.): 1.67–46.6). Remarkably, there were 2 wound infection cases in the post-operation group, which was significantly different from the incidence in the Non-Abx group. The 2 cases of wound infection in the Abx group were both trauma patients. Five patients had wound infection in the early period after PDT, and all of these patients belonged to the Non-Abx group (Fig. 3B). In the post-operation category, the incidence rate of wound infection was also significantly higher in the Non-Abx group. Other outcomes including length

Table 1 Underlying disorders for ICU admission

	Non-Abx group (%)	Abx group (%)	Total (%)
Neurological disorders	27 (39.1)	89 (39.0)	116 (39.1)
Trauma	7 (10.1)	36 (15.8)	43 (14.5)
Respiratory failure	7 (10.1)	35 (15.4)	42 (14.1)
#Post-operation	7 (10.1)	27 (11.8)	34 (11.4)
Cardiopulmonary arrest	10 (14.5)	20 (8.3)	30 (9.8)
Cardiac failure	4 (5.8)	7 (3.1)	11 (3.7)
Sepsis	2 (2.9)	7 (3.1)	9 (3.0)
Airway obstruction	2 (2.9)	4 (1.8)	6 (2.0)
Burn	1 (1.4)	1 (0.4)	2 (0.7)
Renal failure	1 (1.4)	1 (0.4)	2 (0.7)
Intoxication	1 (1.4)	1 (0.4)	2 (0.7)
Total	69	228	297

#A detail of post-operation group included cardiovascular surgery (19 cases), gastrointestinal surgery (10 cases), thoracic surgery (3 cases), head and neck surgery (1 case), and orthopedic surgery (1 case).

Table 2 Baseline characteristics of the patients

	Overall (n = 297)		Neurologic disorders (n = 116)		Trauma (n = 43)		Respiratory failure (n = 42)		Post-operation (n = 34)		CPA (n = 30)	
	Non-Abx (n = 69)	Abx (n = 228)	Non-Abx (n = 27)	Abx (n = 89)	Non-Abx (n = 7)	Abx (n = 36)	Non-Abx (n = 7)	Abx (n = 35)	Non-Abx (n = 7)	Abx (n = 27)	Non-Abx (n = 10)	Abx (n = 20)
Male/Female	34/35	160/68**	11/16	61/28**	4/3	28/8	5/2	21/14	3/4	21/6	4/6	11/9
Age (years)	70.4 ± 12.0	70.5 ± 13.3	67.9 ± 12.9	67.9 ± 13.8	67.7 ± 17.7	68.0 ± 16.1	67.7 ± 10.8	75.6 ± 10.5	78.4 ± 4.0	75.3 ± 11.8	73.5 ± 12.4	67.6 ± 10.6
Albumin (g/dL)	2.7 ± 0.73	2.5 ± 0.64	3.0 ± 0.7	2.7 ± 0.7*	2.7 ± 0.7	2.4 ± 0.5	2.6 ± 0.6	2.4 ± 0.5	2.7 ± 0.8	2.6 ± 0.6	2.3 ± 0.8	2.5 ± 0.8
CRP (mg/dL)	5.8 ± 4.3	8.4 ± 6.8	5.1 ± 3.2	8.8 ± 7.9**	4.8 ± 4.0	9.7 ± 5.3*	5.0 ± 4.1	8.5 ± 6.9	8.3 ± 4.9	6.5 ± 5.4	7.0 ± 6.0	6.8 ± 6.0
PDT after admission (days)	20.7 (2–108)	16.9 (0–247)	17.9 (1–103)	14.8 (1–165)	7.9 (2–14)	16.6 (0–112)	19.4 (10–39)	13.1 (0–56)	34.7 (13–71)	30.9 (0–247)	12.2 (5–29)	9.8 (1–23)
Intubation prior to PDT (days)	11 (0–43)	9.9 (0–42)	11.1 (0–43)	9.1 (0–34)	4.7 (0–10)	10.8 (0–42)*	12.9 (1–26)	7.6 (0–24)	14.6 (0–32)	12.6 (0–37)	10 (0–29)	9.7 (1–23)

CPA, Cardiopulmonary arrest; and CRP, C-reactive protein. Data of age, albumin, and CRP are shown as mean ± standard deviation. *$P<0.05$ and **$P<0.01$ for the comparison with the Non-Abx group. In total, male patients outnumbered female. The tendency was also seen in the group of neurologic disorders. Serum albumin level was lower in Abx group of neurologic disorders, and serum CRP level was lower in both the Abx group of Neurologic disorders and Trauma.

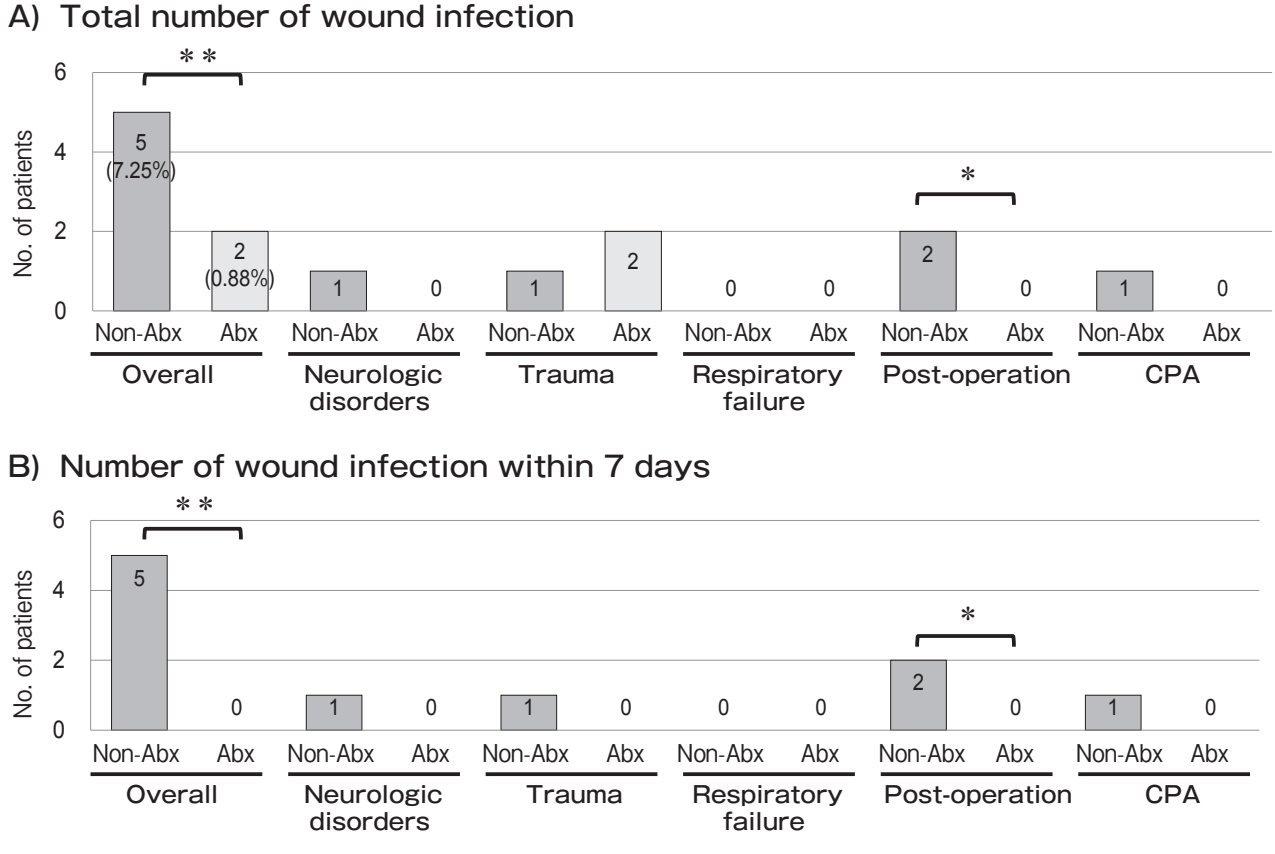

Fig. 3 The occurrence of wound infection after PDT in each group. Panels **A** and **B** show the total number of wound infections and the number of wound infections within 7 days, respectively. Statistical analysis was performed using chi-square test (Fisher's exact test) with Yates' continuity correction. Overall, the occurrence of wound infection was significantly increased in both all subjects (**A**) and early-period subjects (**B**) of the Non-Abx group. The same tendency was confirmed in the Post-operation group. *$p < 0.05$ and **$p < 0.01$ for the comparison with the Non-Abx group.

Table 3 Summary of wound infection cases

	Case	Sex/age	Antibiotics	Occurrence	Underlying disorders	Intervention	Antibiotics for treatment (duration)	Prognosis
Abx group	1	Male/77	Flomoxef, Ciprofloxacin	Day 27	Trauma	none	Azithromycin, 0.5 g (one day)	Cured
	2	Female/80	Cefazolin	Day 18	Trauma	none	none	Cured
Non Abx group	3	Male/79	none	Day 5	Post operation	Surgical drainage	Cefepime, 2 g/day (5 days)	Cured
	4	Male/74	none	Day 7	Post operation	none	Cefcapene pivoxil, 300 mg/day (21 days)	Cured
	5	Female/71	none	Day 5	CPA	Otolaryngologist consultation	Amoxicillin/clavulanate, 1,125 mg/day (14 days)	Cured
	6	Male/53	none	Day 7	Neurological disorder	none	none	Cured
	7	Male/80	none	Day 5	Trauma	none	Ampicillin/sulbactam 9 g/day +Vancomycin 2 g/day (5 days)	Cured

CPA, cardiopulmonary arrest.

of ICU stay after tracheostomy, overall ICU stay, and the periods of hospital stay after tracheostomy were not significantly different between the 2 groups. Of the 7 patients with wound infection, no death or fatal wound infection such as mediastinitis was recorded. The summary of wound infection cases is shown in Table 3.

Discussion

The validity of prophylactic administration of antibiotic remains a matter of debate. As for general surgery, the administration of prophylactic antibiotics is known to reduce the incidence of SSI [14–16]. However, to the best of our knowledge, there is no clear evidence regarding the efficacy of prophylactic antibiotics in preventing wound infections after PDT [12]. A meta-analysis of 6 prospective studies revealed that PDT causes less wound infection than ST does (odds ratio with 95% C.I., 0.02 [0.01–0.07]) [1]. However, the incidence rate of wound infection after PDT is still high: 6% to 7% in a previous study [9] and 7.25% in the Non-Abx group of this study. Patients who receive PDT in the ICU are generally critically ill, and wound infection can increase the mortality rate, extend the length of ICU stay, and give rise to additional costs.

As mentioned above, the superiority of PDT over ST from various points of view has been established. The superiority of PDT can be attributed to differences in the degree of dead space and tissue destruction. ST results in a large dead space around the tracheostomy cannula, while PDT produces less space between the tube and the stomal tissue since the fitting is tight with the surroundings. Less local tissue destruction and consequently decreased exposure of raw skin surfaces after PDT is another possible reason for the lower incidence of infection [9].

The pathogens responsible for wound infections after tracheostomy are considered to be normal bacterial flora of the skin, bronchial mucosa, or oral cavity such as *Staphylococcus* spp. and *Streptococcus* spp.. Various kinds of antibiotics such as β-lactams (*i.e.*, penicillins and cephems), anti-MRSA drugs, and fluoroquinolones were used in this study, and these drugs generally have antibacterial activity against these pathogens. This is also a possible reason for the lower rate of wound infection in the Abx group.

Of the 7 cases of wound infection, 5 cases occurred in the early phase, and all of these belonged to the Non-Abx group. In the Abx group, there were 2 cases of infection, but both occurred more than 2 weeks after PDT: on days 18 and 27. Thus, prophylactic antibiotics may be effective for preventing wound infections in the early phase but have little effect in the late phase. In the early phase after surgical intervention, the tissue is damaged and vulnerable to infection. We assume that antibiotics can prevent the damaged tissue from being infected in the early phase; on the other hand, the preventive effect of prophylactic antibiotics is reduced in the later stage.

The antibiotics were administered not as prophylaxis but as treatment of primary infections in this study, and it is therefore difficult to draw a conclusion regarding the preventive efficacy. The use of antibiotics may lead to a potential risk of emergence of antibiotic-resistant bacteria or the occurrence of *Clostridium difficile* infection. However, the doses and

durations of antibiotics needed for prophylaxis would be less than those needed for treatment. Hence, the negative effect of prophylactic antibiotics would be trivial. Nevertheless, ICU patients always include a wide variety of clinical disorders involving multi-organ damages and possible latent infections. It is therefore very hard to draw definitive conclusions regarding the timing, dose and selection of antibiotics from the results of this retrospective study. In the future, a large prospective randomized trial will be needed to confirm our present results.

In conclusion, the present results suggest that the effectiveness of prophylactic antibiotics for reducing the incidence of wound infection in PDT must be reconsidered, and that the indication for such treatment will involve consideration of the disease category and the clinical condition.

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