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Original Research

Perioperative antibiotic prophylaxis in open tracheostomy: A preliminary randomized controlled trial

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ABSTRACT

Background: The efficacy of perioperative antibiotic prophylaxis for prevention of wound infection in open tracheostomy has been minimally studied and remains controversial.

Methods: A preliminary double-blind, randomized, placebo-controlled trial was conducted. A total of 159 patients who underwent open tracheostomy were enrolled, and 88 patients were excluded because of lack of desire to participate in research, emergency condition, administration of other antibiotics, immunocompromise, or cervical skin infection. The remainings were randomly assigned to an antibiotic group or a control group. Another 11 patients were excluded after the randomization due to intraoperative contamination, death from the underlying disease, receiving other antibiotics, or lost to the follow-up. A total of 30 patients in each group were qualified for analysis. In the antibiotic group, clindamycin was intravenously administered 30 min before the incision and every 8 h after the operation for 24 h. In the control group, an equal volume of sterile saline was administered.

Results: Wound infection developed in 2 patients (6.7%) in the antibiotic group and 7 patients (23.3%) in the control group ($p = 0.08$). In multivariate analysis, smoking and previous neck irradiation were the significant risk factors for wound infection ($p = 0.042$ and 0.019, respectively). The mean length of hospital stay after tracheostomy in patients with and without wound infection were 17 ± 2 days and 4 ± 2 days, respectively ($p = 0.013$).

Conclusion: The result of this preliminary study reveals that antibiotic prophylaxis reduced tracheostomy wound infection rate from 23.3% to 6.7% although it was not statistically significant. However, wound infection may lead to serious complications and prolonged postoperative length of hospital stay, and therefore proper perioperative antibiotics should be considered in patients who are not receiving other antibiotics, and particularly in patients with risk factors for wound infection.

1. Introduction

Tracheostomy is one of the most common operations performed in the hospital [1,2]. It has been done as an emergency or elective procedure [1,2]. Initially, tracheostomy was performed for upper airway obstruction and later the indications were extended to include respiratory failure, prolonged endotracheal intubation and ventilation, pulmonary toilet, and as an adjunct to surgery [1–3]. Open or surgical tracheostomy has been widely accepted as the standard of care for a long period of time and mostly performed in the operating room [1]. Since 1985, when percutaneous dilatational tracheostomy was introduced by Ciaglia [4], the procedure has been rapidly adopted and has increased in popularity because of its safety, convenience, and technical advantages of bedside procedure [1]. However, open tracheostomy still has a main role for emergency situations, difficult neck anatomy, previous tracheostomy, patients with comorbidities, and failure of percutaneous tracheostomy [1].

The incidence of complications associated with open tracheostomy has been reported between 5% and 40% which include hemorrhage, apnea, adjacent tissue injury, tube displacement, subcutaneous emphysema, pneumothorax, and infection [5–7]. The incidence of infection following elective open tracheostomy has been reported up to 33% [8–10]. Tracheotomy is considered a clean-contaminated wound as the procedure enters the upper aerodigestive tract which has bacterial colonization and may also become contaminated by the bacterial flora of the skin especially in urgent or emergency tracheostomy [5,9]. Wound infection may produce serious complications such as tracheitis, mediastinitis, clavicular osteomyelitis, and necrotizing fasciitis [5–7].

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However, perioperative antibiotics to prevent surgical site infection in tracheostomy have not been generally considered because of minimal evidence of their effectiveness [11,12].

The purpose of this randomized controlled trial was to clarify whether antibiotic prophylaxis for open tracheostomy would reduce infection rate and to identify risk factors for tracheostomy wound infection.

2. Materials and methods

2.1. Study design

The preliminary prospective randomized controlled trial was conducted in the Department of Otolaryngology, Faculty of Medicine, between February 2015 and January 2017. The study protocol was performed in compliance with the guidelines for Good Clinical Practice and the Declaration of Helsinki and approved by the institutional ethics committee. All the subjects signed an informed consent form prior to enrollment.

The inclusion criteria were patients between 18 and 85 years of age who had open tracheostomy performed with the following indications: 1) upper airway obstruction from tumor, airway edema or stenosis, neck or maxillofacial trauma, or foreign body, 2) prolonged endotracheal intubation, and 3) facilitating pulmonary toilet.

The exclusion criteria were patients who had immunosuppressive conditions, allergy to clindamycin, diagnosis of cervical skin infection or tracheobronchopulmonary infection, administration of other antibiotics within 7 days before tracheostomy or within 14 days after tracheostomy, and patients who were deceased or unavailable for follow-up in the 30 days after tracheostomy.

The randomization process was carried out using the CONSORT statement 2010 checklist for randomized controlled clinical trials. Patients were assigned in a double-blinded method to either an antibiotic group or a control group. A randomized block design by a computer-generated list was used to allocate patients into the two groups.

The surgery team, the surgeon who instructed patients regarding the intravenous injection and the surgeon who evaluated the wound were all blinded to the allocation group. In addition, the patients were not informed about the contents of injection.

2.2. Surgical technique

Tracheostomy was generally performed in the operating room under general anesthesia or monitored anesthesia care. The patient was positioned with the neck extended. An aqueous solution of 10% povidone-iodine was used for skin disinfection before the operation. A 3–4 cm transverse skin incision was made midway between the sternal notch and cricoid cartilage or two fingerbreadths above the sternal notch. The strap muscles were separated along midline and retracted laterally. The thyroid isthmus was retracted superiorly, inferiorly, or divided. A cruciate incision was made at the second and third tracheal rings. Two stay sutures were used to secure the tracheal opening. The plastic cuffed tracheostomy tube was inserted. The skin incision was not sutured unless it was larger than 5 cm. The tracheostomy tube tape was placed and secured around the neck. A 4x4-inch sterile gauze was cut to allow placement under the tracheostomy tube. In postoperative care, the wound and surrounding skin were cleaned with 70% ethyl alcohol and the sterile gauze was changed twice daily.

2.3. Intervention

Because the common pathogens responsible for tracheostomy wound infection were reported as *Staphylococcus spp.* and *Streptococcus spp* [5,11,13], the selected antibiotic in the study was clindamycin. Patients in the antibiotic prophylaxis group received 100 mL of sterile saline with 600 mg of clindamycin by continuous intravenous infusion 30 min before the surgical incision and every 8 h after the operation for 24 h for a total of 4 doses. An equal volume of sterile saline was administered to the control group in the same manner.

2.4. Follow-up

Surgical site infection is classified as wound infection which occurs within 30 days after the operation [14]. The wounds were carefully examined every day for 30 days by surgeons who were blinded to the randomization. Patients who were discharged from the hospital earlier than day 30 would be instructed to record wound characteristics, and follow-up at day 30 after the operation. The criteria of wound infection included: 1) purulent drainage, 2) identification of organisms, 3) inflammation accompanied by fever or tenderness, 4) abscess or other evidence of infection around the wound detected on gross anatomical or histopathological exam, or imaging test, or 5) diagnosis of a wound infection by the surgeon [14]. Wound discharge was sent for aerobic bacterial culture and sensitivity. Anaerobic bacterial culture was not done because the tracheostomy wound is an open wound and no pus collection in the deep tissues was detected in any patients. The infected wound was managed with intensive local wound dressing, daily tracheostomy tube change, and antibiotics change based on the culture results.

Selected demographic data (sex, age, history of smoking, diabetes mellitus, previous neck irradiation, preoperative albumin level, preoperative hemoglobin level), indication for tracheostomy, and preoperative length of hospital stay were documented and compared between study groups. The outcomes including infection rate, causative organism, duration of postoperative hospitalization, and surgical complication were recorded.

2.5. Statistical analysis

Statistical analyses were performed using SPSS (version 22) for Windows (IBM Corporation, Armonk, NY, USA). Continuous variables were compared using Student's t tests or Mann–Whitney U tests, and categorical variables were compared using chi-square tests or Fisher's exact tests as appropriate. For analysis of risk factors, the chi-square association test was used. Then, a logistic regression model was outlined based on a stepwise forward method testing the significant variables at univariate and multivariate analysis. The risk measure used was the odds ratio (OR), and its respective 95% confidence interval was calculated. Statistical significance was considered for p values less than 0.05.

3. Results

There were 159 eligible patients during the study period. Before randomization, 88 patients were excluded because of lack of desire to participate in research, emergency condition, administration of other antibiotics, immunocompromise, or cervical skin infection. The remaining 71 patients were randomly assigned to either antibiotic group (n = 36) or control group (n = 35). Six patients in the antibiotic group and five patients in the control group were excluded after randomization because of intraoperative contamination, death due to underlying diseases, receipt of other antibiotics during the postoperative period, and loss to follow-up. Therefore, data from 30 patients in each group were analyzed (Fig. 1).

There were no statistically significant intergroup differences in demographic parameters and indication for tracheostomy which confirmed the correct selection of the subjects and randomization of the groups and enabled further analyses (Table 1). Because of the exclusion criteria of no other perioperative antibiotics, the only indication for tracheostomy in this study was upper airway obstruction from tumor or stenosis.

Wound infection was detected in 9 patients with the overall