Pulmonary Complications Following Major Head and Neck Surgery With Tracheostomy

A Prospective, Randomized, Controlled Trial of Prophylactic Antibiotics

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Objective: To test the hypothesis that extended postoperative antibiotic cover would reduce the incidence of pulmonary complications in patients undergoing major head and neck surgery with tracheostomy.

Design: A prospective, randomized, controlled trial was carried out to determine the efficacy of an extended course (5 days) of intravenous amoxicillin–clavulanic acid in reducing the rate of atelectasis and pulmonary infections postoperatively. Other possible risk factors that might predispose to pulmonary complications were also evaluated.

Setting: Tertiary referral center for head and neck surgery.

Patients: Consecutive patients younger than 80 years with planned surgery for carcinoma of the oral cavity, pharynx, or larynx were enrolled. Patients with diabetes, those who had received antibiotics within 1 week before surgery, and those with preexisting pulmonary disease were excluded.

Intervention: Patients were randomly assigned no antibiotics or a 5-day course of intravenous amoxicillin–clavulanic acid postoperatively.

Main Outcome Measures: The development of pulmonary complications (pulmonary infection or atelectasis).

Results: Eighty-six patients were enrolled; 73 patients met the criteria for analysis. Thirty-four (47%) developed pulmonary complications; 29 (40%) had a pulmonary infection. An extended course of antibiotics did not reduce the rate of pulmonary infections ($P = .57$). Positive risk factors for a pulmonary infection were presence of preoperative obstructive lung function and postoperative atelectasis.

Conclusions: An extended course of antibiotics did not prevent the development of postoperative pulmonary infections in patients undergoing major head and neck surgery with tracheostomy. Poor pulmonary function and postoperative atelectasis emerged as significant risk factors for pulmonary infection.


Patients who require a tracheostomy after major head and neck surgery have a high incidence of pulmonary complications that prolong recovery, require more intensive care, delay rehabilitation and discharge from the hospital, and inevitably lead to greater health care costs. Our group previously showed that 45% of patients undergoing major head and neck surgery that involved a tracheostomy develop pulmonary complications, most of which occur in the first 5 days after surgery.1,2 The patients most at risk seem to be elderly people, especially those with comorbid respiratory disease, with poor clearance of lower respiratory secretions.

Antibiotic prophylaxis for major head and neck surgery in which the wound is exposed to oral or pharyngeal bacteria (clean-contaminated surgery) mainly comprises intraoperative cover only.3-5 Few of these studies have involved a prospective, randomized, controlled trial.6,7 There have been many studies investigating pulmonary complications after abdominal or thoracic surgery, where coughing and diaphragmatic movement are reduced postoperatively.8-11 The overall postoperative rate of pneumonia has been reported to be 20% or more. Several risk factors, such as age, obesity, American Society of Anesthesiologists score, preoperative hospitalization, protein depletion, and duration of surgery, have been implicated, but the most important are probably preoperative respiratory function and the presence of preexisting pulmonary disease. The present study was designed to test the hypothesis that extended antibiotic cover would reduce the incidence of pulmonary

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complications in patients undergoing major head and neck surgery with tracheostomy. We also sought to determine whether other risk factors might also play a part in increasing the risk of postoperative pulmonary complications.

**METHODS**

The study included consecutive patients younger than 80 years in whom surgery for carcinoma of the oral cavity, pharynx, or larynx was planned. Patients with diabetes, those who had received antibiotics within 1 week before surgery, and those with preexisting pulmonary disease were excluded. Subjects provided informed consent, and the study was approved by the North Health Ethics Committee.

**PREOPERATIVE ASSESSMENT**

All patients received an assessment of cardiac status, hematologic and biochemical screening, electrocardiogram, chest radiograph, and tests of pulmonary function (forced expiratory volume in 1 second and vital capacity). Static and dynamic lung volumes and flows were determined according to American Thoracic Society standards12 (Vmax 229 Pulmonary Function Analyzer; Sensormedics Corp, Yorba Linda, Calif). European Community Coal and Steel–predicted values were used, and all lung function data were expressed as percentage of the mean predicted values.13 These prediction equations are also appropriate for Pacific Island subjects.14 Serum albumin level, body mass index (calculated as weight in kilograms divided by the square of height in meters), cigarette smoking and tobacco consumption history (pack-years), and alcohol consumption history (units per week) were also determined.

**RANDOMIZATION PROCESS**

Consecutive patients recruited into the study were assigned corresponding consecutive numbers. The antibiotic regimen was determined according to computer-generated random numbers. Odd numbers represented the intraoperative antibiotic regimen (ie, no postoperative antibiotics) and even numbers represented a 5-day course of postoperative antibiotics. The treatment code was sealed inside consecutively numbered envelopes by one of us (R.M.L.W.), a nonclinician, before the commencement of the study. At the end of each patient’s operation, a sealed envelope labeled with the patient’s number was opened and the antibiotic protocol contained therein (ie, intraoperative only or 5 days of prophylactic antibiotics) was instituted.

**MANAGEMENT PROTOCOL**

All patients received a single intravenous dose of 1.2 g of amoxicillin–clavulanic acid at the induction of anaesthesia. This was repeated 6 hours later if the operation was still in progress. Postoperatively, patients were randomly allocated to 5 days of prophylactic antibiotics (1.2 g of amoxicillin–clavulanic acid) or no treatment according to the method described.

All patients were treated initially in an intensive care unit and were transferred to the ward once their clinical status was stable, usually early on the first postoperative day. In the ward, patients received a standard protocol of chest physiotherapy on each of the first 5 postoperative days after surgery. This consisted of a morning visit by the physiotherapist on day 1, instructions to the patients regarding breathing and coughing, and initial assistance to clear secretions. Thereafter, this process was continued by ward nursing staff twice each day. The physiotherapist was further involved at the discretion of the clinicians if difficulties were encountered in clearing secretions. Tracheal suctioning was performed initially every 2 to 4 hours for the first 48 hours and every 8 hours or as required thereafter. Humidification was given continuously for the first 48 hours and was continued at night for 5 days and during the day as required. Monitoring included regular (4-hourly) daily temperature, pulse, and respiration rate recording; daily sputum culture; and record of quality and quantity of sputum production. A daily cardiorespiratory physical examination and daily hematologic screen were performed. Chest radiographs were taken on the second and fifth postoperative days and otherwise as clinically indicated. For those patients receiving postoperative antibiotics, the intravenous additives were delivered every 8 hours until the end of the fifth postoperative day. The clinical and laboratory data were collected by a nonclinical research assistant blinded to the antibiotic regimen that each patient received.

**PRIMARY OUTCOME VARIABLE**

The primary outcome was a pulmonary complication. This was defined as either pulmonary infection or atelectasis. Pulmonary infection was diagnosed if at least 2 of the following criteria were met: persistent (ie, at least 24 hours’ duration) temperature rise above 37.5°C, purulent sputum with a definite increase in volume (>20%), radiologic evidence of new shadowing on chest radiograph, and/or persistent (ie, for 2 or more days) localized signs on chest examination (crackles, bronchial breathing, wheeze, and/or pleural rub). The presence of atelectasis was diagnosed radiologically. All chest radiographs were reviewed by a single respiratory physician (J.K.) who was blinded to the patients’ postoperative therapy.

**TERMINATION CRITERIA**

If a patient developed a pulmonary infection, he or she was deemed to have reached an end point in the study. At that stage, antibiotics were started, resumed, or changed, and the chest physiotherapy regimen was intensified.

**STATISTICAL ANALYSIS**

Results are reported in the form of a 5-day count (percentage). The difference in pulmonary infection between the 2 groups was compared by means of a χ2 test and reported with odds ratio (OR) and 95% confidence interval (CI). Logistic regression was used to assess the relationship between possible risk factors and the development of a pulmonary infection and/or atelectasis, reported as unadjusted ORs and 95% CIs. The statistical software package SAS release 8.0 (SAS Institute Inc, Cary, NC) was used for all analyses. A P value less than .05 was considered significant.

Initial computations indicated that, to detect a 10% improvement in the rate of pulmonary complications with a power of 0.8 and significance level of .05, 80 patients would need to be randomized.

**RESULTS**

A total of 86 patients consented to the study. Thirteen patients (15%) were excluded (5 with no tracheostomy, 8 with protocol violations). Seventy-three patients were included in the study; 37 (27 men, 10 women) received 5 days of prophylactic antibiotics, while 36 (27 men, 9 women) received no antibiotics postoperatively. There were no significant differences in demographics, smoking history, pulmonary function, and postoperative measures between the 2 treatment groups (Table 1). One patient (who was randomized to 5 days of postoperative anti-
of pulmonary infections (11/16 [69%]) than those who  
oral antibiotics did not prevent the develop-

Our study showed that a 5-day course of postoperative prophylactic antibiotics did not prevent the develop-

Table 1. Preoperative and Perioperative Characteristics*  

<table>
<thead>
<tr>
<th>Preoperative characteristics</th>
<th>No Prophylactic Antibiotics (n = 36)</th>
<th>5 d of Prophylactic Antibiotics (n = 37)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex, No. (%) M</td>
<td>27 (75)</td>
<td>27 (73)</td>
</tr>
<tr>
<td>Age, y</td>
<td>60 ± 11</td>
<td>61 ± 12</td>
</tr>
<tr>
<td>BMI</td>
<td>24.5 ± 4.9</td>
<td>26.2 ± 4.8</td>
</tr>
<tr>
<td>Smoking history, pack-years</td>
<td>36 ± 32</td>
<td>21 ± 27</td>
</tr>
<tr>
<td>FEV1/VC ratio</td>
<td>0.68 ± 0.14</td>
<td>0.69 ± 0.10</td>
</tr>
<tr>
<td>White blood cell count, cells/µL</td>
<td>8100 ± 2300</td>
<td>8000 ± 2300</td>
</tr>
<tr>
<td>Operative details, No.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flap reconstruction</td>
<td>16</td>
<td>18</td>
</tr>
<tr>
<td>Mandibullectomy</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>Floor of mouth resection</td>
<td>10</td>
<td>8</td>
</tr>
<tr>
<td>Laryngectomy or pharyngectomy</td>
<td>10</td>
<td>12</td>
</tr>
<tr>
<td>Total</td>
<td>10</td>
<td>12</td>
</tr>
<tr>
<td>Partial</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Postoperative findings</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length of surgery, h</td>
<td>9.0 ± 3.5</td>
<td>9.3 ± 2.9</td>
</tr>
<tr>
<td>Time in ICU, h</td>
<td>12.4 ± 7.5</td>
<td>14.0 ± 6.2</td>
</tr>
<tr>
<td>Frequency of suction, hourly</td>
<td>2.4 ± 1.2</td>
<td>2.8 ± 1.6</td>
</tr>
<tr>
<td>Total days of physiotherapy</td>
<td>6.0 ± 3.3</td>
<td>6.6 ± 3.9</td>
</tr>
<tr>
<td>Day of tracheostomy closure</td>
<td>16 ± 14</td>
<td>14 ± 10</td>
</tr>
<tr>
<td>Day of nasogastric tube removal</td>
<td>13 ± 5</td>
<td>14 ± 6</td>
</tr>
</tbody>
</table>

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters); FEV1, forced expiratory volume in 1 second; ICU, intensive care unit; NA, not applicable; VC, vital capacity.  
*Data are given as mean ± SD unless otherwise stated.

Table 2. Association Between Variables and Developing Pulmonary Complications  

<table>
<thead>
<tr>
<th>Pulmonary Infection</th>
<th>Atelectasis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odds Ratio (95% CI)</td>
<td></td>
</tr>
</tbody>
</table>

Preoperative characteristics  
Sex, No. (%) M  
Age, y  
BMI  
Smoking history, pack-years  
FEV1/VC ratio  
White blood cell count, cells/µL  
Operative details  
Laryngectomy  
Mandibullectomy  
Total days of physiotherapy  
Day of tracheostomy closure  
Day of nasogastric removal  
Atelectasis

Abbreviations: BMI, body mass index; CI, confidence interval; FEV1, forced expiratory volume in 1 second; ICU, intensive care unit; NA, not applicable; VC, vital capacity.

COMMENT

Our study showed that a 5-day course of postoperative prophylactic antibiotics did not prevent the development of pulmonary complications in patients with tracheostomies. The incidence of pulmonary complications was high (47%), consistent with that reported in previous studies by our group. One fifth (22%) of patients developed atelectasis postoperatively and, as a group, were found to be at a much higher risk of pulmonary infection. The most striking risk factor for pulmonary infection was the presence of obstructive lung disease (decreased ratio of forced expiratory volume in 1 second to vital capacity).

The possible impact of postoperative albumin and fluid status was not adequately addressed in this study. We were also unable to assess with multivariate analysis the impact of alcohol consumption, bacteriologic results from sputum cultures, and frequency of suctioning, as missing data rendered the analysis unreliable. It is therefore possible that a type II error exists in our results with respect to these variables. The absence of a significant result in this study suggests that some factor other than antibiotic regimen is determining the development of a pulmonary infection and pulmonary complication.

Rao and coworkers found advanced age, longer smoking history, lower percentage predicted forced expiratory volume in 1 second and peak flow, decreased arterial oxygen pressure, higher degree of dyspnea (Roizen class), presence of a tracheostomy, and prolonged anesthesia to be significant risk factors for a pulmonary complication. In a randomized double-blind study, Weber and coworkers found smoking history, positive cervical nodes, prolonged surgery, requirement for blood transfusions intraoperatively, and postoperative hypoalbuminemia to be possible causative factors. Age, diabetes, choice of antibiotic (ampicillin-sulbactam or clindamycin), nasogastric tube, and presence of a tracheostomy were not significant. A previous retrospective review of 144 major head
and neck procedures identified smoking history to be a significant risk factor for a pulmonary complication, with some suggestion that perioperative antibiotics might have been a factor as well.14,15 Our study is consistent with some of these findings in that we found age and obstructive lung function (probably secondary to cigarette smoking) to be significant predisposing factors. We also identified a trend for prolonged surgery and time in the intensive care unit. Our study suggests that those with a pulmonary infection produced more sputum and hence required more tracheal suctioning. Some form of administration of positive–airway pressure ventilation may therefore play a vital role in preventing the collapse of alveoli postoperatively.

The role of chest wall surgery in the development of postoperative pulmonary complications has been discussed by 2 studies in which patients had head and neck surgery and pectoralis major flap reconstruction. Seikaly et al17 found that two thirds of patients undergoing major head and neck surgery had evidence of atelectasis on chest radiographs postoperatively, with major atelectasis especially being a feature in those who had larger pectoralis major flaps (>40 cm²). The side donating the pectoralis donor flap had no effect on the incidence or severity of atelectasis in either lung. A similar study18 reported a 37% incidence of atelectasis, again with a higher incidence of atelectasis and therefore also the risk of atelectasis needs to be tested. The high prevalence of postoperative pulmonary complications has been discussed by 2 studies in which patients had head and neck surgery with head and neck surgery without such flaps. None of the 5 patients in our study who had pectoralis major flap reconstructions had atelectasis or pulmonary infections.

**CONCLUSIONS**

In this study we have established that patients with compromised lung function carry a particular risk of pulmonary infections. Infection usually supervenes after the development of atelectasis. Neither atelectasis nor pulmonary infection was prevented by a prolonged course of antibiotics in our patients.

We suspect that introduction of either incentive spirometry or positive end-expiratory pressure ventilation in at-risk patients would significantly reduce the incidence of atelectasis and therefore also the risk of infection (and added cost) of pulmonary infections. This hypothesis needs to be tested. The high prevalence of postoperative pulmonary complications after major head and neck surgery makes this a priority area for future research, in our opinion.

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**REFERENCES**