Sputum Retention After Lung Operation: Prospective, Randomized Trial Shows Superiority of Prophylactic Minitracheostomy in High-Risk Patients

Pramod Bonde, MS, FRCS, Ioannis Papachristos, FRCS, Aveen McCraith, BS, Barry Kelly, FRCR, Carol Wilson, MRCP, James A. McGuigan, FRCS, and Kieran McManus, FRCS

Departments of Thoracic Surgery, Physiotherapy, Radiology, and Cardiology, Royal Victoria Hospital, Belfast, Northern Ireland

Background. **Sputum retention after lung operation is a potentially life-threatening condition. The minitracheostomy (Minitrach II, SIMS Portex, Hythe, Kent, UK) is a 4-mm percutaneous cricothyroidotomy device, which allows immediate and repeated aspiration of the tracheobronchial tree by minimally trained staff, and can effectively treat sputum retention. This trial was designed to test the hypothesis that prophylactic minitracheostomy could prevent sputum retention in a high-risk group.**

Methods. **Between March 1997 and October 1999, 102 patients undergoing lung procedures and considered to be at high risk were prospectively randomized to postoperative, prophylactic minitracheostomy insertion in the recovery room with regular aspiration, or to standard postoperative respiratory therapy.**

Results. **Sputum retention developed in 15 patients (30%) in the standard group (n = 52) compared to 1 patient (2%) in the minitracheostomy group (n = 50) ($p < 0.005$). There were three deaths related to sputum retention in the standard group compared to none in minitracheostomy group during the perioperative period.**

Conclusions. **It is possible to identify a group of patients at high risk for sputum retention who will benefit from prophylactic therapy. Minitracheostomy is effective as prophylaxis and treatment.**

(Ann Thorac Surg 2002;74:196–203)

Sputum retention, the failure to clear secretions from the bronchial tree, is a common cause of morbidity and mortality after lung operation. Secretions produced in the lungs are normally transported to the upper trachea by the action of cilia. Efficient clearance requires an effective cough or third party assistance. Handling trauma to the lung, the presence of a thoracotomy wound, and pain prevent adequate coughing in many patients. Retention of major airway secretions may lead to obstruction of bronchopulmonary units and atelectasis. Treatment usually entails frequent nasotracheal suction or repeated flexible bronchoscopy; both techniques are distressing to the patient. Failure to treat adequately leads to pulmonary shunting, pneumonia, systemic sepsis, hypoxia, respiratory failure, and exacerbation of cerebral and cardiac ischemia.

The minitracheostomy (Minitrach II, SIMS Portex, Hythe, Kent, UK) is a 4-mm diameter cricothyroidostomy tube that can be inserted percutaneously [1, 2]. The minitracheostomy allows immediate access to the bronchial tree for regular aspiration by respiratory physiotherapists and can be easily used by nursing staff without specialist training. In addition, the introduction of a catheter into the trachea through the minitracheostomy usually evokes an effective cough effort helping to clear secretions.

Generally minitracheostomy has been introduced into clinical practice without randomized trials. Clinical impressions of the use of minitracheostomy have made many clinicians reluctant to introduce a control arm where patients would be denied minitracheostomy in a controlled trial [3, 4]. There has been one small, randomized trial of minitracheostomy as prophylaxis for all patients undergoing lung operation [5]. Widespread use without selection criteria would mean that many patients would undergo an invasive procedure unnecessarily.

This trial was designed to test the elective prophylactic use of the minitracheostomy in a group of patients with a high incidence of pulmonary and cardiovascular comorbidity who could be predicted to have a significant probability of developing sputum retention.

Patients and Methods

Between March 1997 to October 1999, all patients admitted to a regional tertiary referral unit were considered for inclusion in the trial. Approval was obtained from the research ethics committee, Queen's University, Belfast (ref: 294/96, dated 12/11/1996). Of 468 patients undergoing lung resection, 102 patients met the inclusion criteria and were enrolled in the study. They had full and

Presented at the Thirty-seventh Annual Meeting of The Society of Thoracic Surgeons, New Orleans, LA, Jan 29–31, 2001.

Address reprint requests to Dr McManus, Royal Victoria Hospital, Grosevenor Rd, Belfast, BT12 6BA, Northern Ireland; e-mail: kieran.mcmanus@royalhospitals.n-i.nhs.uk.

Published by Elsevier Science Inc

0003-4975/02/$22.00
PII S0003-4975(02)03612-3

appropriate counseling, and informed consent was obtained. They were randomized to either prophylactic minitracheostomy electively inserted at the end of the operation (minitracheostomy group) or standard respiratory therapy (control group). Randomization was performed postoperatively when the patient had been extubated and stabilized in the recovery room.

Inclusion Criteria

1. Failure to cease tobacco smoking for 6 weeks before the operation.
2. Preoperative forced expiratory volume in 1 second ≤50% of the predicted value for height, weight, and age (≤70% for pneumonectomy).
3. History of ischemic heart disease (presence of current angina pectoris or a history of myocardial infarction).
4. History of cerebrovascular disease, transient ischemic attacks, or complete stroke.
5. Absence or failure of regional analgesia (thoracic epidural or extrapleural intercostal nerve infusion block).
6. Chronic obstructive pulmonary disease, defined as a history of cough productive of sputum on most days for at least 3 months of the year for more than 1 year.
7. Sleeve pulmonary resection with bronchoplastic reimplantation.
8. Resection of the phrenic or recurrent laryngeal nerves.

Exclusion Criteria

1. Patients whose cardiovascular status is unstable intraoperatively or in the immediate postoperative period.
2. Patients who required mechanical ventilation and could not be extubated at the end of the procedure.

The surgical team reserved the option of excluding patients at any time if they considered that the clinical situation precluded inclusion in this trial.

Definitions

STANDARD TREATMENT (CONTROL GROUP). Regional pain relief consisted of either a thoracic epidural (fentanyl and bupivacaine 5 mg/h) or a continuous unilateral infusion of bupivacaine to the intercostal nerves 2 to 10. The latter was delivered through a cannula sited after extrapleural dissection [6, 7], and was augmented by patient-controlled intravenous narcotic analgesia. Where not contraindicated, and in the presence of adequate urine output, nonsteroidal analgesic drugs were also administered. Oxygen was administered by facemask but continuous positive airway pressure was available by mask when required. Nebulized bronchodilators (salbutamol 2.5 mg and budesonide 500 μg twice a day) were commenced preoperatively and continued postoperatively. (ipratropium bromide 500 μg four times a day was added if required). A trained respiratory physiotherapist routinely visited the patient twice daily or more frequently if required. Nasotracheal suction was used if tolerated by the patient. If sputum retention was diagnosed and persisted after the 5-day study period in spite of additional physiotherapy then it was considered that the primary end point has been reached and a therapeutic minitracheostomy was performed. Rigid bronchoscopy was used when there was residual lobar or whole lung atelectasis. The rigid bronchoscope has the advantage that it can be used to rapidly clear the mucus plugs by the availability of wide bore suction and simultaneous positive airway pressure can be applied.

TRIAL TREATMENT (MINITRACHEOSTOMY GROUP). Those randomized to the trial arm had a minitracheostomy inserted in the recovery room. The minitracheostomy was aspirated twice a day routinely for 5 days unless the patient was deemed fit for discharge from hospital before 5 days. More frequent aspiration was performed as indicated by the clinical condition of the patient. Otherwise treatment was the same as in the control arm except that nasotracheal suction was not used. Bronchoscopy was reserved for patients where secretions were not adequately removed by minitracheostomy aspiration.

TECHNIQUE OF INSERTION OF MINITRACHEOSTOMY. The patient is placed in a semierect position with the neck extended over a pillow. Oxygen is administered by mask. Local anesthetic consisting of 2% lignocaine with epinephrine (1:100,000) was injected into the subcutaneous tissues and a vertical 1-cm incision was made in the skin over the cricothyroid membrane. The cricothyroid membrane was incised with a guarded scalpel specifically designed for the purpose and an introducer was inserted; the minitracheostomy was advanced over the introducer and the introducer withdrawn. The minitracheostomy tube was fixed with standard tracheostomy tapes. Secretions are aspirated with a 10F aspiration cannula.

PRIMARY END POINT. The primary end point was sputum retention: the inability to cough significant bronchial secretions from the trachea into the oropharynx. The diagnosis was essentially characterized by evidence of respiratory distress with rapid, shallow, and bubbly respirations with loose large airways rales heard on auscultation. The respiratory physiotherapist diagnosed the sputum retention, which was confirmed by the second opinion of a physician.

SECONDARY END POINTS. In this series rigid bronchoscopy was used to treat sputum retention that could not be cleared using a minitracheostomy alone, where there was persistent white-out of a lung after insertion of minitracheostomy, or where a patient was not stable enough to undergo bedside minitracheostomy.

A chest infection was diagnosed if there was a pyrexia more than 38.5°C, an infective infiltrate or consolidation on chest radiograph, white blood cell count more than 11×10^9 per L, or there was purulent sputum. All suspected chest infections received therapeutic antibiotics.

Chest radiographs were performed for 5 days or until

all drains were removed. These were independently assessed by a radiologist (BK) and the operated and nonoperated lungs scored for atelectasis using the following criteria: 0 = normal; 1a = one-third of hemidiaphragm obscured; 1b = two-thirds of hemidiaphragm obscured; 1c = all of hemidiaphragm obscured; 2 = lobar consolidation; 3 = lobar collapse with consolidation, volume loss, and tracheal deviation; and 4 = bronchial consolidation (whole lung collapse).

The administration of a therapeutic antibiotic other than perioperative prophylaxis (three doses only) for a suspected or diagnosed respiratory infection was also assessed. A number of pneumonectomy patients who did not fulfill all the above criteria for chest infection were treated with antibiotics at the consultant's discretion.

Daily arterial blood gas estimations were carried out. Respiratory failure was defined as the presence of significant hypoxia or hypercarbia (partial pressure of oxygen $<$60 mm Hg, partial pressure of carbon dioxide $>$60 mm Hg), which was accompanied by exhaustion or cardiac dysfunction requiring assisted ventilation

Many patients undergoing lung resection have comorbidity including ischemic heart disease. Experience has shown such patients to be at risk of myocardial infarction should hypoxemia occur in the perioperative period. Cardiac enzymes (creatine kinase MB fraction) and daily electrocardiogram were performed for 3 days postoperatively. All were independently read by a consultant cardiologist (CW) in blinded fashion. Standard electrocardiographic definitions of myocardial infarction, in conjunction with a postoperative increase in creatine kinase MB fraction ($>$10% compared to the total creatine kinase or an absolute value of $>$25 IU/L) were considered as evidence of myocardial infarction and appropriate therapeutic intervention was undertaken.

Any respiratory or cardiac complications, which were a threat to life if left untreated, such as pulmonary edema, fatal arrhythmias, or pulmonary embolism, were recorded and prompt intervention undertaken. Those events, which were clearly secondary to sputum retention (respiratory failure, pneumonia, hypoxic dysrrhythmias, hypoxic crises, acute myocardial infarction), were termed sputum retention-related life-threatening events.

The number of physiotherapy visits was recorded each day for 5 days and the average calculated.

Wherever possible the cause of death was confirmed by postmortem examination. In cases in which the postmortem examination was not possible due to relatives' wishes, the cause of death was determined by the personal clinical evaluation by the senior members of the medical team.

Each end point (except average physiotherapy visits) was represented by a binary categorical variable.

Statistical Analysis

To detect a change from 35% sputum retention in the control group to 10% in the minitracheostomy group, a sample size of 50 patients was required in each group, for a power of 80% and significance level of 0.05. Randomization was done with restricted randomization in a block of size 100, and was implemented by sealed envelopes kept inside the operating room and randomization took place only at the end of the surgical procedure and subsequent stabilization of the patient in the recovery room, to minimize losses through ineligibility.

Treatment groups were compared with respect to risk and end point variables by means of the Fisher's exact test and Mann-Whitney U tests as appropriate. Continuous variables are presented as means $\pm$ standard deviation or as median and 25th to 75th quartiles as appropriate. As many comparisons were performed between the two groups, only a highly statistically significant p value (< 0.05) was considered to reject the null hypothesis of no difference between groups. Odds ratios for sputum retention and their 95% confidence intervals were calculated using binary logistic regression in both univariable and multivariable analyses.

The variables considered were type of treatment, smoking, low forced expiratory volume in 1 second, age, sex, history of ischemic heart disease, chronic obstructive pulmonary disease, previous cerebrovascular accident, absence of regional anesthesia, resection of phrenic and recurrent laryngeal nerves, and sleeve resection. In the multivariable analyses a final model was obtained using a backward stepwise likelihood ratio method and confirmed by a forward stepwise procedure. Data were analyzed using SPSS 9.0 statistical software (SPSS Inc, Chicago, IL).

Results

Fifty of the 102 eligible patients were randomized to the minitracheostomy group and 52 to the control arm. Four patients were excluded due hemodynamic instability or the need for ventilation in the immediate postoperative period. One elderly patient with previous tuberculosis, scheduled for lobectomy and excision of scar carcinoma underwent pneumonectomy because of operative difficulties with calcified hilar nodes. Prophylactic minitracheostomy was mandated by the surgeon and the anesthetist with successful outcome. The study and control arms were comparable for age, gender, operation, and distribution of risk factors (Tables 1 and 2). Both groups had access to the same analgesic techniques and analgesic usage was comparable in both groups.

A statistically significant difference was found between the two study groups in the incidence of postoperative sputum retention (Table 3). Fifteen patients in the control group developed sputum retention compared to only one in the minitracheostomy group ($p < 0.005$). In these 15 patients it was considered that the end point had been reached and 4 patients underwent minitracheostomy insertion to treat the sputum retention on day 5 whereas 6 other patients had the device inserted on day 6. Sputum-related life-threatening events occurred in 7 patients in the control group compared to 1 in the minitracheostomy group ($p = 0.06$).

Table 4 presents the odds ratio for developing sputum retention with respect to risk factors and treatment with prophylactic minitracheostomy; only the latter showed

Table 1. Patient Characteristics and Operative Procedures

Variable	Control Group (n = 52)	MT Group (n = 50)
Age (y)		
Mean age	64.13 ± 9.62	65.34 ± 9.72
Range	39–79	33–78
Sex		
Male	32	39
Female	20	11
Procedure		
Pneumonectomy	7	9
Bilobectomy	3	2
Lobectomy	23	23
Segmentectomy	3	3
Wedge resection	6	5
Lung resection with chest wall resection	2	2
Sleeve resection	2	2
Exploratory thoracotomy and operation fo remphysema	6	4
Analgesia		
Epidural	35	31
Extrapleural & PCA	15	18
PCA only	2	1

MT = minitracheostomy.

statistical significance ($p = 0.004$). The multivariable analyses gave a final model consisting of the treatment variable only, which showed the odds ratio of developing sputum retention was 19.83:1 without the minitracheostomy ($p = 0.004$).

The incidence of secondary end points was comparable between the groups (Table 3). Although respiratory failure was more common in the minitracheostomy group (not significant), this was due to pulmonary embolism in 2 patients and cardiogenic pulmonary edema in the other, neither sputum related.

The radiographic evidence strongly supports the higher incidence of sputum-related respiratory events in those patients not receiving prophylactic minitracheostomy (Table 5). Although there was no difference in atelectasis between the operated and nonoperated lungs, there was a significant difference in atelectasis between the control and treatment groups on all days except the first. The more severe grades of atelectasis (grades 2 and 3) were more common in the control side (n = 10) compared to the minitracheostomy side (n = 1) ($p = 0.005$).

Table 2. Univariable Comparison Between the Groups With Respect to Risk Factors

Risk Factor	Control Group (n = 52)	MT Group (n = 50)	*p* Value
Smoking	30 (57.7%)	28 (56%)	1.00
Low FEV1	5 (9.6%)	11 (22%)	0.10
Ishemic heart disease	21 (40.4%)	12 (24%)	0.09
Absence of regional anesthesia	2 (3.8%)	1 (2%)	1.00
COPD	11 (21.2%)	14 (28%)	0.49
Sleeve resection	2 (3.8%)	2 (4%)	1.00
Phrenic nerve resection	1 (1.9%)	1 (2%)	1.00
Recurrent laryngeal nerve resection	4 (7.7%)	2 (4%)	0.67
Cerebrovascular accident	5 (9.6%)	2 (4%)	0.43

MT = minitracheostomy.

Table 3. Univariable Comparison Between Treatment Groups With Respect to End Points

End Point	Control Group (n = 52)	MT Group (n = 50)	*p* Value
Sputum retention	15 (28.8%)	1 (2%)	<0.005
Bronchoscopy	3 (5.8%)	1 (2%)	0.61
Chest infection	20 (38.5%)	14 (28%)	0.29
Antibiotics (therapeutic)	21 (40.4%)	18 (36%)	0.68
Respiratory failure	1 (1.9%)	3 (6%)	0.35
Myocardial infarction	4 (7.7%)	1 (2%)	0.36
SR-related life-threatening events	7 (13.5%)	1 (2%)	0.06
Life-threatening events	9 (17.3%)	7 (14%)	0.78
Average physiotherapy visits per day.	1.88 ± 0.93	1.73 ± 0.72	0.60

MT = minitracheostomy; SR = sputum retention.

Five patients developed minor complications related to minitracheostomy insertion. In 2, the minitracheostomy tracked cephalad into the larynx and another inserted too laterally through the thyroid cartilage. In each patient the problem was immediately identified and the minitracheostomy reinserted in the correct position without any further complications. One patient developed transient hoarseness for which no cause was found, but was settled in 6 weeks with speech therapy. One patient needed reinsertion of the minitracheostomy due to accidental removal.

Although there was no statistically significant difference detected between the two groups with regard to the respiratory physiotherapists' visits, there was a difference in the visits needed in the patients who developed sputum retention. The average physiotherapy visits needed per day in patients who developed sputum retention was 2.75 ± 1.01 compared to 1.63 ± 0.67 ($p < 0.001$) in those who did not (Fig 1).

There were 3 in-hospital deaths in each group. The three deaths in the control group all followed sputum retention and were confirmed at autopsy to be due to pneumonia (postoperative days 6, 7, and 11). The last of these had developed a cerebellar infarction in addition to sputum retention; autopsy confirmed both the infarction and extensive chest infection. Of the three deaths that occurred in the minitracheostomy group 2 were proven on autopsy to be due to pulmonary embolism (one on day 14 and the other on day 24 after transfer to a convalescent hospital). The third was a patient who developed renal failure and subsequent pulmonary

Table 4. Univariable Analyses of Risk Factors as Predictors of Sputum Retention[a]

Variable	*p* Value	Odds Ratio	95% CI (lower)	95% CI (upper)
Smoking	0.54	1.38	0.47	4.04
Low FEV_1	0.28	3.16	0.38	25.84
Ischemic heart disease	0.63	1.31	0.43	3.97
COPD	0.96	1.03	0.30	3.54
CVA	0.34	2.31	0.40	13.12
Minitracheostomy versus standard treatment	0.004	19.83	2.50	156.80

[a] Odds ratio for the variables sleeve resection, phrenic nerve resection, recurrent laryngeal nerve resection, and absence of regional anesthesia cannot be accurately calculated.

CI = confidence interval; COPD = chronic obstructive pulmonary disease; CVA = cerebrovascular accident; FEV_1 = forced expiratory volume in 1 second.

Table 5. Atelectasis Score, Operated and Nonoperated Lungs (Days 1 to 5)

Postoperative Day	Normal	At[a]	1a	1b	1c	2	3	4	Pn#[b]	*p* Value
First day										
Operated side										
Control	33/45 (73.33%)	12	5	4	3	0	0	0	7	0.04
Study group	37/41 (90.24%)	4	1	2	1	0	0	0	9	
Nonoperated side										
Control	39/52 (75%)	13	5	5	3	0	0	0	...	0.12
Study group	43/50 (86%)	7	3	2	2	0	0	0	...	
Second day										
Operated side										
Control	25/45 (55.55%)	20	6	6	7	1	0	0	7	0.006
Study group	34/41 (82.92%)	7	3	2	2	0	0	0	9	
Nonoperated side										
Control	21/52 (40.38%)	31	9	10	8	3	1	0	...	<0.001
Study group	38/50 (76%)	12	4	3	4	1	0	0	...	
Third day										
Operated side										
Control	18/45 (40%)	27	8	8	7	2	1	1[c]	7	<0.001
Study group	32/41 (78.04%)	9	3	3	2	0	0	1[c]	9	
Nonoperated side										
Control	18/52 (34.61%)	34	9	10	9	4	1	1[c]	...	<0.001
Study group	38/50 (76%)	12	4	3	4	1	0	0	...	
Fourth day										
Operated side										
Control	25/45 (55.55%)	20	5	4	5	2	3	1[c]	7	0.002
Study group	35/41 (85.36%)	6	2	2	2	0	0	0	9	
Nonoperated side										
Control	29/52 (57.69%)	23	5	6	6	4	1	1[c]	...	0.003
Study group	42/50 (84%)	8	2	3	2	1	0	0	...	
Fifth day										
Operated side										
Control	32/45 (71.11%)	13	4	2	3	2	2	0	7	0.05
Study group	36/41 (87.80%)	5	2	2	1	0	0	0	9	
Nonoperated side										
Control	37/52 (71.15%)	15	4	4	3	3	1	0	...	0.015
Study group	45/50 (90%)	5	2	2	1	0	0	0	...	

[a] Total number of patients with atelectasis. [b] Pneumonectomy. [c] Needed bronchoscopy.

Atelectasis score: 0 = normal; 1a = 1/3 of hemidiaphragm obscured; 1b = 2/3 of hemidiaphragm obscured; 1c = all of hemidiaphragm obscured; 2 = lobar consolidation; 3 = lobar collapse with consolidation, volume loss, and tracheal deviation; 4 = bronchial consolidation (whole lung).

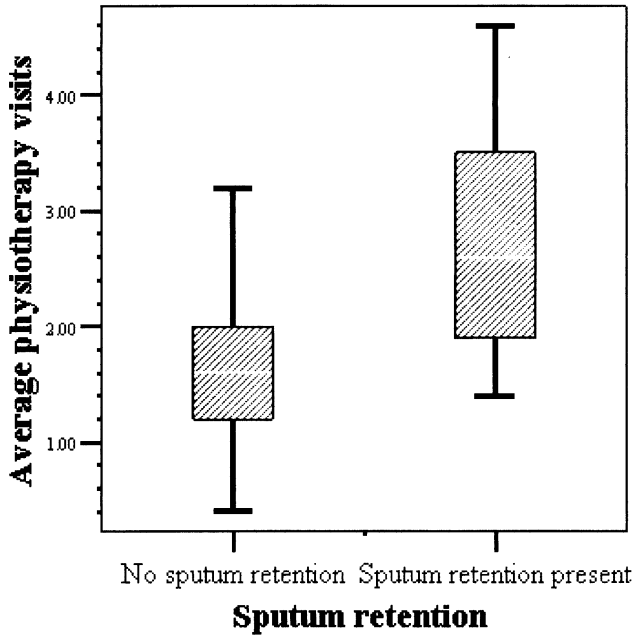

Fig 1. Average physiotherapist visits per day.

edema, but declined intensive care and ventilation. A further patient required ventilation for pulmonary edema after renal failure and was able to be weaned after treatment.

Comment

Prophylactic minitracheostomy reduced the incidence of sputum retention from 29% to 2% in this series of patients who were at high risk for respiratory complications after lung operation. The sequence of events leading to sputum retention is more common in those with chronic lung disease and smokers because of increased production of secretions, particularly in the perioperative phase [1]. Sleeve resection of the bronchus may impair transport of secretions to the trachea. Failure to control pain and intraoperative injury to recurrent laryngeal and phrenic nerves impair coughing. In those patients in whom ischemic heart disease was the only indication for minitracheostomy, the incidence of respiratory complications was not elevated compared to a group of standard risk patients. This was probably related to many of them giving up cigarettes at the time of diagnosis of ischemic heart disease. However, when patients with ischemic heart disease develop hypoxia as the result of a respiratory event, the results may be catastrophic. (Of the 2 patients who developed acute myocardial infarction secondary to sputum retention in this study, both needed inotropic support and developed acute renal failure.) Therefore, it should remain a relative indication for prophylactic minitracheostomy (or other prophylaxis). The history of cerebrovascular disease reflects the likelihood of coronary vascular disease. In addition, previous strokes may be exacerbated by anesthesia, major surgery, or by postoperative hypoxia interfering with the patient's ability to cooperate fully with physiotherapy.

Sputum-related deaths were also reduced by prophylactic minitracheostomy. In the control group deaths, there was a clear sequence of sputum retention, clinical chest infection (followed in 1 patient by cerebellar stroke), and an independently performed autopsy confirming the presence of chest infection. The minitracheostomy group deaths did not have this sequence and pulmonary embolism was diagnosed at autopsy in 2 patients and there was a clear sequence of renal failure followed by pulmonary edema in the third patient.

Nasotracheal suction can be used to pass the vocal cords and remove secretions from the trachea, but it requires the skills of an experienced respiratory therapist and is poorly tolerated by many patients [8]. Flexible bronchoscopy requires trained bronchoscopists and is uncomfortable for patients. There is often a significant delay from diagnosis to bronchoscopy and it frequently requires repetition. Cricothyroidotomy and minitracheostomy, in particular, have been used extensively to treat sputum retention [9–11]. The advantages of minitracheostomy are that it is a ward procedure, performed under local anesthetic, and requires minimal attention. Sputum aspiration through the cannula can be performed by nursing, medical, or physiotherapy staff without specialist training.

A possible criticism of the trial design is that minitracheostomy insertion was possible in both arms of the trial. It is important to note that the purpose of the trial was not to prove the efficacy of minitracheostomy as a treatment for sputum retention (we believe the existing literature supports this and the message is confirmed by the study). The aim was to test the hypothesis that prophylactic minitracheostomy would reduce the incidence of sputum retention in the first place. All means other than minitracheostomy were used to prevent sputum retention in the control group, and during the study our physiotherapists were anxious to show the efficacy of their techniques, seeing sputum retention as a failure on their behalf. But once sputum retention was diagnosed the primary end point had been reached. Once the end point was reached, all methods were used, including minitracheostomy on 10 occasions.

It was not possible to design a crossover in this postoperative trial as the factors causing sputum retention are time related—the risk of sputum retention is highest at approximately 24 to 48 hours after which pain is reduced, drains are removed, and mobility improves.

Chest infections occurred in 38.5% of patients in the control group and 28% in the minitracheostomy group. Allowing for other variables, this difference did not achieve statistical significance ($p > 0.29$). The incidence of lung infections was relatively high in both groups. It is a valid criticism of the study that perhaps our threshold for the diagnosis of chest infection was too low. However, this was a group of patients selected as high risk and should not be compared to routine cases. In pilot studies

we did not find Gram stain or culture to be useful in making a diagnosis of infection, although it did assist in fine-tuning antibiotic therapy. In these patients with long-standing lung disease, Gram stain usually produces mixed flora whether contaminant, overgrowth of normal flora, or true pathogen. Our microbiologists are unprepared to make a call of infection on that basis. Detecting and treating chronic low-grade infections or "colonizations" before operation may reduce postoperative infection [12].

Deciding when pulmonary sepsis is actually present after lung operation is not straightforward and for a study like this it is a relatively "soft" end point. The roentgenographic changes are subtle in the first few days after operation (Table 5) and the more obvious lobar changes are predated by clinical findings and the need for increased physiotherapy visits. Surgeons have to be pragmatic, particularly in patients having pneumonectomy after neoadjuvant chemotherapy, and must act one step ahead of radiologic and laboratory findings. If this study does no more than to emphasize a proactive approach, it will have achieved its purpose. In terms of sputum retention, the ultimate proactivity is prophylaxis. Although there were only minor complications in this study, significant complications associated with minitracheostomy insertion have been reported [13, 14]. Therefore, we would still recommend that prophylactic use be restricted to this high-risk group.

Physiotherapy visits were more frequent (2.75 ± 1.01 per day) in those who developed sputum retention. In those without sputum retention, the rate was (1.63 ± 0.67 per day). In all patients the principle of avoiding minitracheostomy insertion or bronchoscopy was maintained in favor of intensive physiotherapy. With the higher rate of sputum retention in the control group (28.8%) as opposed to the minitracheostomy group (2%) and a significant increase in physiotherapy visits in the sputum retention patients (1.88 ± 0.93 per day versus 1.73 ± 0.72 per day), there is a cost implication in the treatment of established sputum. Minitracheostomy is an inexpensive device with low associated costs and may have significant economic advantages.

In conclusion, it is possible to identify a group of patients at high risk for the development of sputum retention after lung operation, although the criteria used here may need to be further defined. The study clearly demonstrates the benefit of using prophylactic measures (in this case minitracheostomy, although regular bedside bronchoscopy may also be successful) to reduce sputum retention and its complications in this high-risk group. In this study minitracheostomy was effectively used, both as prophylaxis against and for treatment of sputum retention.

We thank Dr Gordon Cran, medical statistician, Queen's University of Belfast, for the support given regarding the statistical analysis. We also thank Moyra Mills, thoracic research nurse, for the collection and collation of data. Ms Mills was supported in part by a grant from SIMS Portex, Hythe, Kent, UK, who also made available the minitracheostomy kits free of cost during the trial period.

References

1. Matthews HR, Hopkinson RB. Treatment of sputum retention by minitracheotomy. Br J Surg 1984;71:147–50.
2. Merkle NM, Schluter M, Foitzik T. Minitracheotomy: a new interventional technique for treatment of sputum retention. Surg Endosc 1992;6:199–204.
3. Albertario F, Mapelli A. Considerations on 200 cases of percutaneous cricothyroidotomy (minitracheotomy). Monaldi Arch Chest Dis 1993;48:272–4.
4. Joosten U, Meyer G, Rupp D, Hohlbach G. The value of mini-tracheotomy as a new interventional technique in treatment of postoperative tracheobronchial retention of secretions. Results of a prospective study of 152 surgical intensive care patients. Anasthesiol Intensivmed Notfallmed Schmerzther 1994;29:210–20.
5. Randell TT, Tierala EK, Lepantalo MJ, Lindgren L. Prophylactic minitracheostomy after thoracotomy: a prospective, random control, clinical trial. Eur J Surg 1991;157:501–4.
6. Sabanathan S, Mearns AJ, Bickford Smith PJ, et al. Efficacy of continuous extrapleural intercostal nerve block on post-thoracotomy pain and pulmonary mechanics [see comments]. Br J Surg 1990;77:221–5.
7. Barron DJ, Tolan MJ, Lea RE. A randomized controlled trial of continuous extra-pleural analgesia post-thoracotomy: efficacy and choice of local anaesthetic. Eur J Anaesthesiol 1999;16:236–45.
8. American Association for Respiratory Care. AARC clinical practice guideline. Nasotracheal suctioning. Respir Care 1992;37:898–901.
9. Buckels NJ, Khan ZH, Irwin ST, Gibbons JR. Post-operative sputum retention treated by minitracheostomy–a ward procedure? Br J Clin Pract 1990;44:169–71.
10. Pedersen J, Schurizek BA, Melsen NC, Juhl B. Is minitracheotomy a simple and safe procedure? A prospective investigation in the intensive care unit. Intensive Care Med 1991;17:333–5.
11. Au J, Walker WS, Inglis D, Cameron EW. Percutaneous cricothyroidostomy (minitracheostomy) for bronchial toilet: results of therapeutic and prophylactic use. Ann Thorac Surg 1989;48:850–2.
12. Wansbrough-Jones MH, Nelson A, New L, Wilson A, Wright N, Pepper JR. Bronchoalveolar lavage in the prediction of post-thoracotomy chest infection. Eur J Cardiothorac Surg 1991;5:433–4.
13. Allen PW, Thornton M. Oesophageal perforation with minitracheostomy [letter; comment]. Intensive Care Med 1989;15:543.
14. Charnley RM, Verma R. Inhalation of a minitracheotomy tube. Intensive Care Med 1986;12:108–9.

DISCUSSION

DR LESLIE J. KOHMAN (Syracuse, New York): I would like to ask how many people in the audience use a technique like this, either with this method or some other method like this, on a regular basis? (A show of hands, perhaps 1/4 to 1/3 of the audience.)

DR YUJI SHIRAISHI (Kiyose, Tokyo, Japan): I enjoyed your presentation. I have one question.

When we look at the data, in the group having standard treatment about 40% of patients had chest infection. Therefore,

the incidence of chest infection seems very high. Could you tell us about the criteria for chest infection? Do they just include pneumonia or also include other types of infection such as empyema?

DR BONDE: Thank you for your comment. The chest infection occurred in about 39% of the patients in the control group versus 28% in the minitracheostomy group, and we accept as a valid criticism of the study that perhaps our threshold for diagnosis of chest infection was too low. However, after lung resection, most of the clinicians prefer to overdiagnose chest infection and treat possible lung infection, particularly in those patients who have undergone a pneumonectomy or those who received chemotherapy. Our criteria for chest infection was basically a fever more than 38.5°, or a white cell count more than 11, or evidence of purulent secretions and signs of sepsis.