Clinical Experience and Physiologic Results with an Implantable Intratracheal Oxygen Catheter*

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Ten patients with chronic lung disease received an implanted ITOC. Seven patients continue to use their catheters after a mean period of 14.75 months. Four catheters were removed, 2 at 1 month, 1 after 10 months and 1 after 13 months. One patient requested a second catheter. Three patients experienced mucus plug formation; this was transient in two patients, but led to removal of the catheter in the third. To determine the degree of oxygen-saving afforded by the ITOC, SaO₂ was measured at rest and during exercise for eight of the ten subjects using a double-blind technique. The calculated oxygen savings were around 40 percent both at rest and during exercise. The ITOCs were well received by the majority of our patients and were shown to produce a useful saving of oxygen which is of benefit to patients using portable systems and those who require high oxygen flow rates. (Chest 1992; 102:1413-18)

DOMICILIARY oxygen is usually administered via a face mask or nasal cannulae, but transtracheal delivery has several advantages over the more traditional routes.\(^1\) The major benefit is the reduction of the flow rate required to maintain adequate oxygenation. This allows prolonged use of portable oxygen systems and adequate oxygenation of patients who require high flow rates. Studies of percutaneous transtracheal catheters have demonstrated reductions in the flow rate of around 50 percent. Other advantages include improved comfort and compliance with treatment. Conventional transtracheal catheters are, however, readily visible and require removal and reinsertion for cleaning. Some transtracheal catheters are liable to produce subcutaneous infection, catheter fracture and displacement,\(^2\) which may make them unattractive to the patient and physician.

This article describes our clinical experience with a tunneled intratracheal catheter which offers the benefits of transtracheal oxygen delivery with fewer drawbacks than the alternative designs. Our early experience with this catheter was encouraging\(^3\) and has now been extended to ten patients.

MATERIALS AND METHODS

Subjects

The patients selected for the procedure all had chronic airflow obstruction or restrictive lung disease (Table 1). This was deemed severe enough to require oxygen therapy either continuously in order to improve their prognosis\(^4\) or intermittently to improve exertional breathlessness. One subject could not safely receive nocturnal oxygen using nasal cannulae without unpredictable elevation of her arterial PCO₂ because of changes of respiratory route and of cannula positioning during the night. The patients were all receiving maximal medical treatment for their respiratory disorders. This was unchanged for at least four weeks prior to insertion of the catheter and there had been no recent exacerbation of their illness. All patients had a careful physical examination to exclude an anatomic abnormality of the neck such as a goiter. Eight of the subjects performed the physiologic study (subjects 1, 3 and 5 to 10). All eight were studied at rest but one (subject 5) was unable to complete the exercise test. Patients 2 and 4 did not undergo any physiologic investigations because their catheters had been removed before the investigations were commenced.

The Catheter-Insertion and Postoperative Care

A 43-cm 11-F gauge Silicon catheter was used (Cook Critical Care ITOC catheter).\(^5\) The proximal end of the catheter which lies within the trachea is short and is directed caudally (Fig 1). The risk of displacement is reduced by a round Dacron-covered fixation disc which is sutured to the external wall of the trachea. A Dacron tissue ingrowth cuff is situated approximately two thirds of the way along the catheter to aid fixation in the subcutaneous tunnel. The catheter

FIGURE 1. The intratracheal oxygen catheter

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exit site is placed conveniently below the costal margin.

The implantation procedures all were performed with the subjects under local anesthesia and additional intravenous sedation. A perioperative antibiotic cover of benzylpenicillin and fluoxazacillin was used.

The catheters were flushed four times daily with 2 ml of sterile saline solution followed by 3 ml of air immediately postoperatively. Antibiotic cover was continued with fluoxazacillin for three weeks until the lower Dacron cuff was fixed in position. Oxygen administration through the catheter was delayed for an arbitrary period of five to seven days; early use of the catheter is thought to dry the intratracheal site and may delay healing and promote the formation of mucus plugs. An attempt was made to avoid violent coughing during the early postoperative period in order to minimize the risk of cervical subcutaneous emphysema. In all patients, the oxygen delivered through the catheters was not humidified. Direct traction on the catheter should be avoided at all times.

**Physiologic Study Method**

In both the rest and exercise studies, the subjects had nasal cannulae in position as well as tubing connected to their intratracheal catheters. Oxygen was delivered at varying flow rates in increments of 0.5 or 1 L/min, with the rate and route of delivery randomized. The SaO₂ was measured using a pulse oximeter (Biox 3700) and was recorded by an observer who was blind to both the flow rate and route of delivery.

In the rest of the study, the patient was seated in a quiet room and flow rates of between 0.5 and 4 L/min were delivered. The SaO₂ was recorded when its value remained stable for at least 5 min.

The exercise studies consisted of repeated 2-min walks on a horizontal treadmill. The speed was determined individually as the mean speed during a prior 6-min corridor walk test. The range of treadmill speeds was 0.6 to 2.5 miles per hour (mean, 1 mile per hour). Oxygen was delivered at rates between 0.5 and 6 L/min. The SaO₂ values at the end of each walk and the lowest value recorded during the walk or in the recovery phase were recorded. After each walk, the subjects were allowed to rest until their SaO₂ and pulse had returned to pre-walk values with an arbitrary additional rest period of 10 min.

**RESULTS**

**Clinical Results and Complications**

The procedure itself was tolerated well by all of our patients and no significant intraoperative complications occurred. No patient experienced hemorrhage from the tracheostomy site and hemoptysis was either minimal or absent. The catheter was positioned successfully in the trachea in all of our patients, although in one, suturing of the tracheal disc was incomplete because of technical difficulty. The total operative time ranged from 30 to 50 min.

Small areas of subcutaneous emphysema around the tracheal site were noted in three patients in the immediate postoperative period. This resolved spontaneously within two days. Patients 2 and 9 developed increased dyspnea two to four weeks after the procedure as a result of the formation of a mucus plug around the intratracheal portion of the catheter. We performed bronchoscopy with the rigid bronchoscope on these patients as a rapid and reliably effective method for the removal of the mucus plugs. Patient 2 had been flushing his catheter inadequately and this problem did not recur following correction of the technique. In patient 9, two further significant mucus plugs developed, causing respiratory embarrassment requiring further bronchoscopy. The patient subsequently developed inflammation at the tracheostomy incision site which did not settle. The ITOC was removed and at removal a marked granulation tissue response was found to have developed on the tracheal wall and was thought to have caused the repeated mucus plug formation. Following removal of the ITOC, the patient did not develop any evidence of tracheal stricture.

Patient 4, in whom suture of the tracheal disc was incomplete, developed subcutaneous emphysema and mild inflammation around the proximal site three weeks postoperatively. Radiography of the neck and fiberoptic bronchoscopy confirmed that the catheter had become displaced in the neck and it was removed through the subcutaneous tunnel. Patient 1 developed inflammation of the exit site due to protrusion of the cuff. This was caused by the lower Dacron cuff being too low and its displacement through the exit hole by inadvertent traction on the catheter before fixation by tissue ingrowth had taken place. The inflammation settled for a period but recurred three months later. The ITOC was removed at that time, but at the patient's request, a second catheter was inserted four months later. The catheters of patients 2 and 7 fractured at the distal end adjacent to the oxygen

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**Table 1 — Characteristics of the Patients**

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age</th>
<th>Sex</th>
<th>FEV₁ (L)</th>
<th>FVC (L)</th>
<th>PaO₂ (kPa)</th>
<th>PaCO₂ (kPa)</th>
<th>Diagnosis</th>
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<td>f</td>
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<tr>
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<tr>
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<td>m</td>
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adapter connection 16 and 13 months post-insertion, respectively. In both cases, they were repaired using a simple repair kit. None of the catheters fractured at any other site.

Patient 8 was admitted to the hospital with an infective exacerbation of emphysema three months post-insertion. She developed respiratory failure and needed endotracheal intubation and ventilation for five days. The endotracheal tube was shortened slightly for this purpose and the ITOC continued to function well. She experienced two episodes of mucus plug formation post-extubation but none afterward.

Seven patients continue to use their ITOCs. Patient 6 was able to return to work following insertion of the catheter. Patient 1 has since married. Of the four catheters removed, 2 were at 1 month, 1 at 10 months and 1 at 13 months. Of the 7 catheters in situ at present the mean duration of catheter implantation is 14.75 months (range, 4 to 22 months). The duration of catheter implantation is summarized in Figure 2.

**Physiologic Results**

**Rest study:** The SaO₂ values were plotted against oxygen flow rates as dose-response curves. For each patient, the difference in SaO₂ between the lowest value when breathing air and the highest obtained with oxygen delivered through nasal cannulae was divided into quartiles. The interpolated flow rates that would achieve the quartile SaO₂ values were used to calculate the percentage of oxygen saving when using the ITOC (Fig 3).

The mean percentage flow rate reductions for the eight patients at rest, derived from all of the quartile points, was 42 percent (95 percent CI, 38 to 46 percent).

If the comparison was made to determine the flow rates required to achieve the maximum SaO₂ reached using nasal cannulae only (the fourth quartile point) the mean change at rest was 51 percent (95 percent CI, 46 to 56 percent).

**Exercise Study:** The SaO₂ values again were plotted against oxygen flow rates to represent the differing prevention of desaturation during a standardized exercise test with the ITOC and nasal cannulae. The savings of oxygen flow rates to maintain the quartile SaO₂ values were calculated in the same way as for the rest study.

From all of the quartile points and using the SaO₂ values at the end of each walk the mean reduction in flow rate calculated was 40.5 percent (94 percent CI, 35.9 to 45.1 percent), and using the lowest SaO₂ values obtained during each walk the mean oxygen saving was 41.3 percent (95 percent CI, 36.8 to 45.8 percent).

If the comparison was made at the maximum SaO₂ maintained using nasal cannulae (fourth quartile point), using the end exercise SaO₂ values, the mean flow rate reduction was 37.3 percent (95 percent CI, 25.9 to 48.7 percent), and using the lowest SaO₂ values the mean change was 40.7 percent (95 percent CI, 31.5 to 40.9 percent). These results are summarized in Figure 4.

**Discussion**

Transtracheal delivery of oxygen has several reported advantages compared with use of nasal cannulae. It lessens the flow rate required to maintain adequate oxygenation. The discomfort of nasal cannulae and face masks is removed and the device may improve patient compliance with long periods of oxygen treatment and lead to an improved quality of life. Lastly, patients may report reduced sensation of dyspnea which may occur because of decreased work.
of breathing resulting from a reduced inspired minute ventilation.\textsuperscript{11}

Conventional transtracheal oxygen catheters have a number of drawbacks. Despite being less obtrusive than nasal cannulae or face masks, the visible catheter and insertion site are not cosmetically acceptable to all patients. The catheters are usually fixed with a necklace, but despite this, they may become displaced with a risk of loss of the insertion track.\textsuperscript{12} Conventional catheters usually have a long intratracheal portion which is liable to fracture\textsuperscript{4,13} or cephalad displacement and which is thought to increase mucus ball formation in the trachea. This may form a mass large enough to threaten major airway obstruction\textsuperscript{14} and death if un-

Two recent series clearly have documented the complications of transtracheal oxygen therapy using the SCOOP system. Adamo et al\textsuperscript{16} reported a total of 120 complications in 21 patients during a 20-month period (with a mean follow-up period of 7.7 months). In that series many of the complications were not clinically significant but included two catheter misplacements into the mediastinum; one patient had significant hemoptysis and one developed upper airway obstruction and acute respiratory failure as a result of a large inspissated tracheal cast. There were eight episodes of stomal or neck infection in six patients. While cleaning catheters, 8 patients experienced 11 episodes of inability to reinsert catheters into developed tracts and 7 patients experienced dislodgement of catheters on a total of 9 occasions—usually at night—requiring 5 repeat procedures. Two patients developed excessive external stomal granulation tissue. Hoffman et al\textsuperscript{17} recently reported a series of 40 patients again using the SCOOP system. Ten (25 percent) of these patients experienced symptomatic mucus balls in the early phase. There were 18 episodes of catheter displacement with 6 lost tracts. Four patients had a probable bacterial cellulitis, one a cephalad displaced catheter and one a severed cathe-

![Figure 4. Summary of oxygen savings. A, at rest; B, on exercise using the \(\text{SaO}_2\) values at the end of each walk; C, on exercise using the lowest values obtained during each walk. Cross line represents the mean and vertical bar the 95 percent CI. Top, Oxygen saving results calculated from all savings at all quartile points on all subjects (ie, across the whole range of flows). Bottom, Oxygen savings calculated using the fourth quartile points only (ie, the saving of oxygen to achieve the maximum \(\text{SaO}_2\) that was produced while using nasal cannulae).](image)

![Figure 5. The postoperative appearance.](image)
ter. Five patients elected to discontinue its use.

The design of the catheter used in this study reduces some of these problems. It is cosmetically superior since it is invisible at the neck (Fig 5). The tubing leaves the skin in the subcostal region and is easily concealed in clothing. The fixation of the catheter is secure providing the disc is adequately sutured to the tracheal wall, and the effect of traction on the distal end is ameliorated by the Dacron tissue ingrowth cuff. In one of our patients, however, inadequate surgical access prevented complete suture fixation of the tracheal disc, leading to subsequent displacement. In a second patient, early inadvertent traction on the catheter displaced the lower Dacron cuff but not the tracheal portion of the catheter.

The neck site is closed and the long subcutaneous tunnel minimizes the risk of contamination of the neck wound. The seal provided by the fixation disc prevents infection of the neck from purulent secretions within the trachea. The design of the catheter with a short intratracheal portion is intended to reduce the risk of formation of mucus plugs. This problem has occurred in our patients only if there has been a problem with compliance with flushing of the catheter following endotracheal intubation or as a result of an unusual granulosity reaction in the tracheal wall. All three of these patients had an FEV\(_1\) less than 0.5 L/min, which by limiting the effectiveness of their cough may have predisposed them to mucus plug formation. The catheter is not removed for cleaning and therefore there is no risk of loss of the insertion track or of extratracheal placement. Two of the ITOCs fractured, but in both cases it was at the proximal end adjacent to the oxygen connection adapter and not in the subcutaneous or intratracheal portions.

The reduction of oxygen flow rate requirements using transtracheal catheters arises as a result of at least two mechanisms. First, wastage around the nose and mouth is obviated. Second, the oxygenated dead space of the upper trachea, larynx and pharynx is greatly reduced.

Several authors have documented a range of oxygen savings at rest with percutaneous transtracheal catheters, but there are few accurate data regarding the reduction of flow rate on exercise when such reductions are most useful and no results of savings with a tunneled catheter.

Heimlich and Carr\(^{13}\) reported a 57 percent reduction at rest while maintaining therapeutic arterial blood gases. Using nasal cannulae, Leger et al\(^{18}\) reported a reduction from a mean (SD) of 4.89 (1.67) L/min to 2.89 (1.08) L/min to achieve a mean resting PaO\(_2\) of 9.71 ± 0.67 kPa. Banner and Govan\(^{2}\) achieved a 50 percent reduction of oxygen flow rate to reach a mean resting PaO\(_2\) of 9.3 kPa. Hoffman et al\(^{3}\) reported a 55 percent reduction at rest with patients achieving similar exercise times using less oxygen through a transtracheal catheter. In a later study, Hoffman et al\(^{17}\) reported an oxygen flow rate reduction of between 25 and 50 percent. Christopher et al\(^{4}\) reported a 55 percent reduction at rest and a 30 percent reduction during exercise while allowing patients to walk at their own pace for 10 min. Heimlich and Carr\(^{14}\) have shown a 44 percent mean reduction in a group of 200 patients and Adamo et al\(^{15}\) reported a mean reduction of 37 percent to provide a similar level of oxygen saturation.

Our physiologic study has shown a reduction of oxygen flow rate requirements of around 40 percent both at rest and also during a standardized exercise test. This saving is very similar to the results previously obtained with percutaneous catheters with a long intratracheal section.

There are two main groups of patients who will benefit from the savings afforded by ITOC. First, those who require high flow rates to achieve adequate oxygenation at rest will benefit. Using conventional nasal cannulae and an oxygen concentrator, high flow rates may be uncomfortable and poorly tolerated by the patient. Compliance with treatment is vital to achieve the reported benefits of long-term oxygen therapy. Additionally, in a few such patients the oxygen concentrator may not be able to deliver the high flow rates required.

The second group is comprised of those who gain symptomatic benefit from portable oxygen systems. Their duration is increased in proportion to the oxygen conservation which, with the tunneled intratracheal catheter, is approximately 40 percent.

Our experience with this group of patients confirms that the ITOC is an efficient and well-tolerated device for giving supplemental oxygen when it cannot be adequately provided by conventional means. An operative procedure is required for its insertion which is not needed for percutaneous transtracheal catheters, but it does not have the drawbacks of dislodgement and misplacement associated with these catheters which require removal, cleaning and replacement. It is, in addition, cosmetically superior. An ITOC, like other transtracheal devices, should only be used when there is a firm indication for this route of delivery and the patients who are selected for its use must be well motivated in order to comply with the daily care routine.

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Plan to Attend ACCP's XVII World Congress on Diseases of the Chest

Implantable Intratracheal Oxygen Catheter (Jackson et al.)