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Transtracheal oxygen therapy: an effective and safe alternative to nasal oxygen administration

M.J. Kampelmacher*, M. Deenstra**, R.G. van Kesteren*, C.F. Melissant**, J.M.C. Douze*, J-W.J. Lammers**

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ABSTRACT: Transtracheal oxygen therapy (TTOT) improves the efficiency of oxygen delivery and overcomes the discomfort associated with nasal oxygen delivery in patients on long-term oxygen therapy (LTOT). In addition, TTOT improves compliance and quality of life, and may reduce morbidity. Experience with TTOT in Europe is, however, scarce and the safety of TTOT has not yet been completely determined. These were reasons for testing the acceptance, efficacy and safety of TTOT.

Patients were selected on the basis of the accepted indications and contraindications for TTOT. In 75 patients (48 males and 27 females) the mean follow-up time was 16 (range 0.5–51.5) months.

Compared to nasal cannulae, TTOT caused a reduction in the oxygen flow rate of 47 (33–60)% at rest and a significant increase in the number of hours that oxygen was used. All patients on TTOT used oxygen for at least 20 h·day^{-1}. Most patients saw the procedure as a minor intervention. It was usually performed on an out-patient basis. In 34 patients, 51 mainly minor complications were seen, and most of these occurred in the first 10 patients. After precautions had been taken, complications occurred less frequently. No patient needed to be hospitalized because of a complication. TTOT had to be stopped in two patients; nevertheless, all patients preferred TTOT to the nasal cannulae.

We conclude that transtracheal oxygen therapy is an effective and safe alternative to nasal oxygen administration, provided that it is restricted to a well-defined group of patients and applied by a motivated and experienced group of physicians.
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*Centre for Home Mechanical Ventilation, Division of Internal Medicine and Dermatology and **Dept of Pulmonary diseases, Heart Lung Institute, University Hospital Utrecht, Utrecht, The Netherlands.

Correspondence: M.J. Kampelmacher
Centre for Home Mechanical Ventilation
HP B 00.118
University Hospital Utrecht
P.O. Box, 3508 GA Utrecht
The Netherlands

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In patients on long-term oxygen therapy (LTOT), oxygen is usually administered by nasal delivery devices. The discomfort associated with these devices may cause poor compliance. This can worsen the patient's prognosis, since it has been demonstrated in patients with chronic obstructive pulmonary disease (COPD) that LTOT prolongs survival if oxygen is used for at least 15 h·day^{-1} [1, 2]. Besides being uncomfortable, nasal oxygen delivery devices are inefficient. Only 15–20% of the oxygen administered during a respiratory cycle takes part in alveolar gas exchange. The rest is lost at the end of the inspiration and during expiration [3].

The transtracheal microcatheter (TTMC) delivers oxygen directly into the trachea through a small opening between the first and second tracheal ring. Transtracheal oxygen therapy (TTOT) improves the efficiency of oxygen delivery by creating an oxygen reservoir in the trachea and larynx. Consequently, mean oxygen savings amount to 50% at rest and 30% during exercise [4–7]. TTOT reduces dead space ventilation and inspired minute ventilation, while increasing alveolar ventilation slightly, which may result in a reduction of the oxygen cost of breathing [8–11]. As a result, patients using TTOT may experience improved exercise tolerance and reduced dyspnoea [12, 13]. Obviously, the treatment avoids the discomfort and complications of nasal delivery devices. In addition, it was shown that TTOT improved quality of life and reduced the haematocrit, pulmonary vascular resistance, hospitalization, incidence of infectious exacerbations and mortality [7, 14–19]. Apart from these advantages, there are the disadvantages of the invasiveness of the procedure and the potential for complications.

Since 1980, TTOT has been applied worldwide in over 10,000 patients, particularly in the USA [20]. Since its introduction, TTOT has been found to offer more than oxygen conservation. Until recently, experience with TTOT was scarce in Europe. The aim of this study was to assess the acceptance, efficacy and safety of TTOT in Dutch patients on LTOT.

Methods

Subjects

Patients were selected on the basis of an indication for LTOT and by virtue of the accepted indications and

contraindications for TTOT [6, 7], Ten patients out of 96 were already hospitalized when presented for TTOT by their chest physician or internist. Five of the 10 hospitalized patients, and 10 out of 86 out-patient candidates were rejected for TTOT because of contraindications. In total, 76 out-patients were given at least 1 week to consider TTOT; and six decided to refuse this form of treatment. Therefore, 70 out-patients and five hospitalized patients underwent the treatment, provided that their disease had remained stable.

Original protocol

According to the SCOOP protocol, TTOT consists of four clinically-defined phases [7, 21]. In phase I, potential candidates are informed and suitable patients selected. Phase II consists of the transtracheal procedure followed by 1 week of stent placement. Phase III starts when the stent is exchanged for a SCOOP-1 catheter, which has one distal port. Because the tract is immature, the patient is instructed to clean the TTMC *in situ*. Phase IV begins 6–8 weeks after the procedure. Most tracts will be mature by this time and patients are instructed to remove the catheter for cleaning. Patients with resting flow rates >2 $L \cdot min^{-1}$ may begin using a SCOOP-2 catheter, which has multiple side-ports in addition to the distal opening.

Adjusted protocol

Over recent years we have adjusted the original SCOOP protocol. In the present study, patients were given an intravenous catheter for emergency use and were monitored with a pulse oximeter and an electrocardiogram (ECG) monitor during the insertion. After the eighth patient, stripping of the SCOOP-1 catheter over a wire guide was performed weekly during phase III. From the fourteenth patient onwards, the lock of the necklace was sealed with tape and the necklace was secured to the skin of the neck by two pieces of tape immediately right and left of the flange [22, 23]. After an incidental occurrence of haemoptysis following the use of a cleaning rod whilst cleaning *in situ*, we advised against its use from the sixteenth patient onwards. Finally, from the nineteenth patient onwards, a SCOOP-1 instead of a SCOOP-2 catheter was used during phase IV, since it seemed that the latter caused more coughing and sputum production.

Measurements

The need for oxygen flow was assessed by pulse oximetry. Compliance with oxygen therapy was computed from the files of the oxygen suppliers. Survival was calculated from the date of the (first) transtracheal procedure until death, or up to the closing date of the study.

Statistical analysis

Comparisons between groups with different types of lung disease were made using one-way analysis of variance (ANOVA). Pearson's correlation coefficients were calculated to determine associations between oxygen savings and patients' ages, and resting oxygen flow rates. Univariate analysis of survival was performed using the Kaplan-Meier method, and a rank order test was used for comparing survival between groups [24, 25]. Two-sided tests were applied throughout and a p-value less than 0.05 was considered significant. Numerical variables are expressed as mean±SD. Data were processed using the Statistical Products and Service Solutions (SPSS)/PC+ program (SPSS Inc., Chicago, USA).

Results

Patients and procedure

Between February 5, 1990 and March 1, 1996, 81 procedures were performed in 75 patients, whose characteristics are listed in table 1, and whose diseases are presented in table 2. In 70 patients, a SCOOP catheter (Transtracheal Systems, Englewood, USA) was initially used. Five patients started with an Oxycath catheter (Laboratoire Smad, Larbresle, France) but were transferred to a SCOOP catheter after a spontaneous tear occurred in the external part of one of the Oxycaths. Operation time ranged 20–30 min, irrespective of the operator. The first seven patients were hospitalized for 1 night as a precautionary measure. Afterwards, the procedure was performed in eight patients who had been admitted to another hospital, either to undergo this operation or because of an exacerbation of their disease. The other 60 patients were treated on an out-patient basis.

Table 1. – Characteristics of patients (n=75)

Characteristic		
Sex ratio M/F	48/27	
Age at time of procedure yrs	61	(28–79)
P_{a,O_2} kPa	6.9	(6.5–8.1)
P_{a,CO_2} kPa	6.3	(4.1–7.7)
FEV_1 L	0.8	(0.5–1.3)
Duration of LTOT months	23	(1–144)
Patients using liquid oxygen %	100	
Last oxygen flow rate $L \cdot min^{-1}$	2.1	(0.5–14.0)
Travelling distance km	67	(5–180)

Values are presented as mean, and range in parenthesis, unless otherwise stated. M: male; F: female; P_{a,O_2} and P_{a,CO_2}: arterial oxygen and carbon dioxide tension, respectively; FEV_1: forced expiratory volume in one second; LTOT: long-term oxygen therapy.

Table 2. – Primary diagnoses of patients (n=75)

Diagnosis		
COPD	48	(64)
Pulmonary fibrosis	14	(19)
Pulmonary emboli	3	(4)
Scleroderma	2	(3)
Pneumoconiosis	2	(3)
Cystic fibrosis	1	(1)
Primary pulmonary hypertension	1	(1)
Kyphoscoliosis	1	(1)
Histiocytosis-X	1	(1)
Lymphangitis carcinomatosa	1	(1)
Lymphangioleiomyomatosis	1	(1)

Values are presented as absolute number, and percentage in parenthesis. COPD: chronic obstructive pulmonary disease.

Acceptance

TTOT had to be stopped in one patient because of unexpected severe anxiety and lack of co-operation, and in a second patient who did not tolerate the treatment. TTOT was also stopped in a patient who underwent a lung transplant 2 weeks after the procedure, and did not need LTOT thereafter. Hence, since no patient preferred to go back to the nasal cannulae, overall acceptance was 73 out of 75 patients (97%).

Four patients needed mechanical ventilation during phase IV because of respiratory insufficiency due to a pulmonary infection unrelated to the use of TTOT. Intubation was not impeded by the TTMC. After they had been extubated, all patients could resume TTOT without difficulty.

Table 3. – Follow-up, survival and oxygen usage of patients (n=75)

Mean follow-up time months	16	(0.5–51.5)
Follow-up ≥24 months n (%)	18	(24)
Died by March 1, 1996 n (%)	33	(44)
Mean TTMC oxygen flow rate $L \cdot min^{-1}$	1.0	(0.25–7.0)
Mean oxygen savings %	47	(33–60)

TTMC: transtracheal microcatheter.

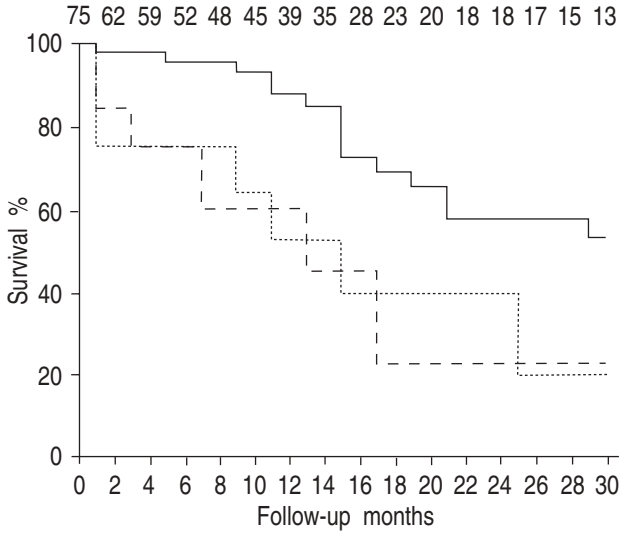

Fig. 1. – Proportional survival of patients with COPD (———), pulmonary fibrosis (--------) and other diseases (·····) following the (first) transtracheal procedure. The number of patients at risk are shown at the top of the diagram. COPD: chronic obstructive pulmonary disease.

Oxygen usage

With the nasal cannulae, oxygen was used for less than 15 and 20 h daily by 24 (32%) and 38 (51%) patients, respectively. With the TTMC, all patients used oxygen for more than 20 $h \cdot day^{-1}$, and 68 (91%) patients used it continuously. Mean oxygen savings and mean TTMC flow rates are shown in table 3. Oxygen savings were independent of age, disease or nasal oxygen flow rate.

Survival

Data on follow-up time and survival are presented in table 3 and figure 1. Proportional survival was best for patients with COPD and significantly different from the pooled groups of non-COPD patients (p=0.0017). Six patients who were in a terminal phase of their illness died before they had a mature tract, four of them within 3 weeks after the procedure.

Complications

A total of 51 complications occurred in 34 patients (table 4). The number of complications per patient averaged 0.7 (range 0–5). The most serious condition was closure of the tract after the TTMC had been lost. This happened to seven patients, but only once after the lock had been sealed and the necklace taped to the neck. All

Table 4. – Frequency of complications caused by TTOT in the first 10 patients, the next 65 patients, and according to the literature

Phase and nature of complication	Patients (n=10)		Patients (n=65)		Frequency %	[Refs.]
Phase II						
Subcutaneous emphysema	-		2	(3)	0–27	[26, 31]
Phase III						
Upward-displaced catheter	7	(70)	-		0–66	[17, 22, 27, 31]
Lost tract	6	(60)	1	(2)	0–24	[7, 17, 22, 28]
Chondritis	3	(30)	2	(3)	0–10	[28]
Keloid formation	2	(20)	3	(5)	0–4	[7]
Inadvertent dislodgement of catheter	2	(20)	2	(3)	0–57	[22, 28, 31]
Fractured catheter	1	(10)	-		0–24	[4, 22, 31]
Cricothyroid puncture	-		1	(2)	0–3	[7]
Symptomatic mucous ball	1	(10)	-		0–38	[17, 22, 23, 30, 31]
Tracheobronchitis	-		1	(2)	0–43	[28, 30]
Bacterial cellulitis	1	(10)	-		0–30	[17, 22, 29, 30]
Tracheitis	-		1	(2)	0–14	[22, 30]
Phase IV						
Patient unable to reinsert catheter	3	(30)	5	(8)	7–22	[17, 22]
Keloid formation	2	(20)	5	(8)	4–7	[7, 17, 22]
Total	28		23			

TTOT: transtracheal oxygen therapy. Values in parentheses are percentages of the group. For details of the phases in the SCOOP protocol see the text.

seven patients wanted to recontinue TTOT. Twelve patients lost the TTMC without tract closure. Seven of them were able to reinsert the TTMC at home after instructions by telephone. Five patients had to visit the hospital for reinsertion. The patients showing signs of tracheal chondritis and the patient with cellulitis responded well to an extra course of antibiotics for 1–2 weeks. For nine patients with a keloid or granulation tissue, simple cautery with an $AgNO_3$ stick was sufficient. In one patient, the granulation tissue had to be excised.

Four patients were suspected of having granulation tissue obstructing the trachea, since their dyspnoea continued despite regular catheter stripping. However, bronchoscopy did not reveal any irregularities. One of the first patients, a 72 year old lady with pulmonary emboli, was at first rejected for TTOT because of several relative contraindications. Three months later, she was hospitalized elsewhere because of progressive hypoxaemia on nasal oxygen. Even on TTOT (flow rate 7 $L \cdot min^{-1}$) her hypoxaemia persisted. She died 3 weeks after the procedure. Autopsy revealed an almost complete obstruction of her trachea by granulation tissue.

With the exception of the latter patient and the patients with a lost tract, all complications were transient and clinically unimportant. No patient needed to be hospitalized because of a complication, nor did any patient die as a result of TTOT. Two patients had to be seen during the night because of inadvertent dislodgement of the catheter during phase III. In the remainder, all complaints could be handled during the daytime.

Discussion

This study demonstrates that TTOT can be an effective and safe alternative to nasal oxygen administration in carefully selected patients. Resting oxygen savings amounted to 47%, which is consistent with data from the literature [6, 7]. The increase in the number of hours of daily oxygen use by TTOT patients is an important result, which may positively influence survival. The patients in the Nocturnal Oxygen Therapy Trial (NOTT) study who had the best chance of surviving used oxygen for 17.7 $h \cdot day^{-1}$ [1, 20]. TTOT patients using oxygen continuously may have an even better chance of survival. Many of our patients stated that they went out more often while using oxygen. This may have been due to the fact that they felt less self-conscious.

One noteworthy fact is that practically all complications were temporary and clinically unimportant. The varying frequency of complications quoted in the literature has several causes. Firstly, the occurrence of a learning effect is very likely. Whilst in studies of more than 50 patients the incidence of difficulties is moderate, it is quite high in most smaller studies [26–29]. In the present study, more than half of the complications occurred in the first 10 patients. RAI *et al.* [30] showed that the incidence of complications did not decrease with the number of patients. However, in their study, common complaints, such as a transient increase in coughing and sputum volume and transient tenderness, were regarded as complications. Moreover, the fact that the first 20 patients were using a lower oxygen flow rate than the last 31 patients might explain the higher incidence of mucous balls in the latter. Noninfectious complications decreased slightly as experience increased.

Secondly, the type of catheter is important. Compared to more flexible catheters, like the SCOOP, stiffer ones, like the Angiocath and Oxycath, may cause less mucous balls, but they seem to crack and break off sooner [4, 26, 31]. The standard internal length of 11 cm may prove to be too long in shorter patients and in patients whose lungs are retracted. This can cause obstruction of the catheter and may result in the formation of mucous balls [32]. So far, complications reported from the Netherlands have always been caused by oxygen catheters implanted into the trachea (ITO_2C; Cook Critical Care, Bloomington, USA) [33–35]. The implantation and the removal of the catheter have to be performed under local anaesthesia and intravenous sedation, which involves a certain risk for the patient [36]. In fact, compared to the TTMC, the incidence of serious complications caused by the ITO_2C is much higher [37].

Thirdly, the travelling time to the clinic and availability of an experienced physician or nurse may be important. Finally, the frequency of problems may be influenced by the aftercare offered, particularly during phase III [22]. The low incidence of tracheitis and mucous balls in the present series of patients, for example, could be ascribed to the advice given from the sixteenth patient onwards to refrain from using the cleaning rod whilst cleaning *in situ* [38].

Unfortunately, a number of studies have disputed the safety of TTOT [33–42]. This scepticism is, however, misplaced. The incidence of clinically important complications is very low [6, 20]. Most are temporary and not serious and many could, to a large extent, have been avoided by taking simple precautionary measures (table 5). Many of the patients in whom a mucous ball was reported, for instance, were not seen weekly. In the USA this is clearly related to travelling distance [22]. Most of these patients were in phase III and were using high oxygen flow rates. Since it is well-known that these patients are susceptible to mucous ball development, weekly catheter stripping over a wire guide should be performed. Furthermore, adequate humidification of oxygen is of crucial importance in these patients [21, 22]. These negative reports have presumably caused reluctance to TTOT in Europe. However, TTOT has recently become

Table 5. – Recommendations to reduce the number of complications caused by TTOT

1. Call the patient after the procedure
2. Wait at least one week with oxygen administration through the catheter
3. Give the patient verbal and written instructions
4. Strip the catheter over the wire guide once a week
5. See to assistance while stripping the catheter
6. Seal the lock of the security necklace with tape
7. Affix the necklace immediately right and left of the flange with tape on the neck
8. Secure the availability of an experienced physician
9. Do not use materials of inferior quality
10. Stress the importance of adequate humidification
11. Do not rely too much on the help of unexperienced persons
12. Do not treat patients in a (pre-)terminal stage of their disease

TTOT: transtracheal oxygen therapy.

increasingly popular in Switzerland (Zürich), Germany (Homburg, Cologne and Munich) and Norway (Bergen). In France (Lyon and Paris) the Oxycath is still utilized to some extent.

Despite the fact that 45% of our patients experienced at least one complication, not one patient considered using the nasal cannulae again. The high acceptance rate of 97% is comparable to that in a study in which the same catheter type was used [7]. Potential candidates for TTOT should be selected with care. Candidates should be offered detailed information because of the high amount of self-administered care and need for cooperation, and to decrease potential fears. To avoid disappointment after the patient has changed to TTOT, unrealistic expectations should be readjusted in advance. The ideal candidate for the treatment has a strong desire to remain active, is willing to follow the protocol, is not troubled by frequent exacerbations, has a caregiver who is willing to assist with problem-solving and details of care, and lives within 2 h of a clinic with a skilled medical team [6]. Postinsertion care requires considerable patient reliability and support from such a team. Unfortunately, some physicians still fail to recognize that TTOT is not a procedure but an entire programme for LTOT.

In conclusion, in this paper we have described our first experience with transtracheal oxygen therapy in 75 patients. Apart from oxygen savings, the programme has a potential for medical benefits, such as optimizing oxygen usage and decreasing hospitalization. Creation of the tract is the simplest part of the therapeutic programme. The aftercare is very demanding both for the patient and physician. Transtracheal oxygen therapy is an effective and safe alternative to nasal oxygen administration, provided that it is restricted to a well-defined group of patients and is applied by a motivated and experienced group of physicians. In our view, the doubts which have been raised about the safety of transtracheal oxygen therapy are, therefore, unjustified.

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