Krankheitsverlauf bei schwerer COPD mit und ohne Physiotherapie mit dem RC-Cornet®

Eine randomisierte 2-Jahres-Langzeitstudie
Pneumologie 2002; 56: 418-424

Translation

Course of Severe COPD with and without Physiotherapy with the RC-Cornet®.

A Randomized 2 Years Long-term study

Introduction

Drug therapy of COPD patients, especially in advanced stages, is an unsatisfying and thankless procedure. The therapeutic problem is due on the one hand to the fact that the obstruction itself is conditioned by reversible changes in the bronchial tree (contraction of the smooth musculature, increased mucus production, reduced mucociliary clearance, inactivation and reduction of surfactant). On the other hand, further factors contributing to the obstruction include a number of dysfunctions that do not respond to drug therapy (e.g. reduced elastic reactivity of pulmonary tissue, instability of the tracheobronchial system) [1, 2]. The last-mentioned disturbance results in a "mechanical" obstruction of the respiratory tract in forced expiration and coughing; in addition to this, the increase in functional residual capacity due to "trapped air" means increased respiratory work [3].

Studies have shown that physiotherapeutic measures can make a manifestly causal contribution to drug therapy efficacy [4]. Effectiveness of physical therapy in COPD is considered to be evidence-based [3]. This is reflected in the recommendations issued by specialist associations and professional groups on COPD therapy [5, 6]. Physiotherapy is mentioned within the framework of the overall programme of rehabilitative measures in the international recommendations, and here in particular in "GOLD" [7]. Oscillating PEP systems (RC-Cornet®, Flutter®) are specially recommended for the physiotherapy [6, 10].

In addition to the physiotherapeutic efficacy of these oscillating PEP systems, we also demonstrated in a randomized, short-term study involving COPD patients that the bronchodilatative effect, for example of ipratropium bromide, is significantly increased by cotemporal application of oscillating PEP therapy (RC-Cornet®) [8].

The present paper investigates the following questions:
1. Are pulmonary function parameters influenced differently in COPD cases receiving the same drug treatment by additional physiotherapy with the RC-Cornet® (combined PEP) over a period of 2 years?
2. Does the additional physiotherapy influence the frequency of hospitalization in COPD patients?
3. Does the duration of hospitalization differ in these patient groups?
4. Are there differences in the frequency of infections requiring antibiotic treatments in the two patient groups?
Method
Study design

In the present study, 50 patients suffering from severe COPD (mean FEV1 41%, mean single-breath DLCO 51% of standard), trapped-air in the body plethysmographic resistance loop and check-valve mechanism in the flow-volume curve were randomized into 2 groups of 25 patients each (Tab. 1).

<table>
<thead>
<tr>
<th>Tab. 1 Demographic data</th>
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<tr>
<td>Medication only</td>
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<td>Medication plus</td>
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<tr>
<td>RC-Cornet®</td>
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<td>n</td>
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<tr>
<td>Age (Y)</td>
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<tr>
<td>Sex</td>
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<td>Height (m)</td>
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The two groups received the same drug treatment:

Theophylline according to serum levels, inhalations of long-acting beta-2 sympathicomimetics (Salmeterol, dosed aerosol, 1 stroke twice a day), ipratropium bromide (Atrovent®, 2 strokes three times a day), systemic glucocorticosteroids with 5 mg of prednisolone equivalent per day. Accompanying therapy of other conditions was individually adapted (diabetes, osteoporosis).

The first group of 25 patients received only the above-mentioned drug therapy as per earlier recommendations [9].

The second groups received the same drug therapy plus respiratory physiotherapy with the RC-Cornet® in the starting position. Duration of therapy was at least 5 minutes 3 times a day. The following recommendation was also given: "Use the device whenever you notice mucus or dyspnoea."

The exclusion criteria were smoking, right and left cardiac decompensation and an infection at the beginning of the initial examination. The patients also had to be able to walk. The medication group had smoked for 20.2 ± 8.1 pack years and the group receiving additional physiotherapy had smoked for 22.3 ± 8.7 pack years.

Following medical history and clinical examination, each patient was subjected to a pulmonary function analysis. The initial functional analysis involved a body plethysmography and a flow-volume curve1, followed by a broncholytic test using a Salbulair® autohaler, 2 inhalations each, after 15 minutes re-measurement of body plethysmographic parameters. An arterial blood gas analysis was also carried out on the hyperaemic earlobe and oxygen saturation was measured.

Control examinations as described above were carried out during the first year at 3-month intervals and in the second year at 4-month intervals.

Theophylline and cortisol levels, medication consumption volumes and wear, functionality and setting of the RC-Cornet® were also registered in a compliance check. The patients were also reminded at every examination of the necessity to take the medication regularly and, in the relevant group, to make use of the additional RC-Cornet® physiotherapy.

The pulmonary function measurements were carried out at around 11 a.m. on the examination days after medication and one session of physiotherapy with the RC-Cornet® had been done in the morning. Use of the RC-Cornet® was not allowed during the last hour before measurement of pulmonary function.

Of the initial 81 patients, usable data over the 2-year period was obtained for 53 (27 patients in the CR-Cornet® group and 26 in the "medication only" therapy group). Using a random generator, 2 cases were eliminated from the CR-Cornet® group and 1 from the "medication only" group, so that evaluation could cover exactly 2 x 25 patients.

The statistical evaluation of the results was done with the program Statistica from Statsoft, Version 6, 2001 edition, Statsoft Inc., Tulsa, Oklahoma, USA.

The tests used were the 4-field table, chi-square test, Wilcoxon test, sign test and regression calculation.

The RC-Cornet® is a handy physiotherapy device for patient self-therapy that produces a "combined PEP" when the patient blows into it in the starting position and in position 1, i.e. it builds up a continuous positive pressure of about 20 cm head of water when blown into

Movement of the ventilation tube of the RC-Cornet®

Continuous positive pressure builds up because the air from the 2nd compartment is not expelled until the 1st compartment has reclosed.

1 Bodyscope from Ganshorn Elektronik, Niederlauer
with additional pressure oscillations of about 5 cm head of water depending on how strongly the patient blows (see Fig. 1).

Three pressure oscillation frequencies are superimposed (see Fig. 2): A low frequency at about 20 Hz, a middle frequency at 80 Hz and a high frequency pressure oscillation of 300 Hz.

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Further details have been published in this journal [10].

Besides the pressure oscillations, airflow oscillations are also generated by expiration (see Fig. 2): These pressure and airflow oscillations are imparted to the bronchial tree by way of the mouthpiece, causing calibre fluctuations in the bronchi and resulting in increased collateral ventilation because due to the continuous positive pressure. This improves a) mucociliary clearance b) fluid clearance and c) pulmonary hyperdistension is reduced [11, 12].

Compliance

Monitoring of theophylline levels revealed no measurable theophylline level in both groups at 20 different time points during the study; at the other times of measurement, the theophylline levels were measurable within the therapeutic range.

<table>
<thead>
<tr>
<th>Medication only</th>
<th>Medication plus RC-Cornet®</th>
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<tbody>
<tr>
<td>FEV1 (l/s)</td>
<td>1.18 ± 0.45</td>
</tr>
<tr>
<td>following broncholysis</td>
<td>1.26 ± 0.46</td>
</tr>
<tr>
<td>VC (l)</td>
<td>2.54 ± 0.63</td>
</tr>
<tr>
<td>Raw (kPa.s/l)</td>
<td>0.63 ± 0.2</td>
</tr>
<tr>
<td>TGV (l)</td>
<td>4.76 ± 0.65</td>
</tr>
<tr>
<td>FEV1 % of standard</td>
<td>41.9 ± 13.9</td>
</tr>
<tr>
<td>VC % of standard</td>
<td>65.4 ± 13.8</td>
</tr>
<tr>
<td>TGV % of standard</td>
<td>140.8 ± 18.3</td>
</tr>
</tbody>
</table>

The cortisol level controls revealed remained at baseline, or even lower, at all control time points.

Checking of the RC-Cornet® revealed functionality and tube abrasion at all monitoring time points; the patients also reported regular device use.

### Pulmonary function

At the beginning, no significant differences were observed for the lung parameters between the two groups (Tab. 2). Figs. 3 and 4 show the mean values and standard deviations of the pulmonary function parameters airway resistance and vital capacity in % of standard level in the course of the study. A 1 following a parameter on the abscissa indicates the initial baseline value (e.g. RT1 = baseline resistance value). A 2 indicates the measured value after 3 months. RT3 is the measured value after 6 months, RT4 after 9 months, RT5 after 12 months and RT6 is the first measurement in the second year, i.e. after 16 months, RT7 in the 20th month and RT8 after 2 years.

The time points 1-8 are used for all parameters. The diagrams reflect seasonal variations in the pulmonary function parameters [13]. Variations similar to those for VC...
and airway resistance were also observed for FEV1, in % of standard and thoracic gas volume in % of standard.

We began with a correlation analysis of these mean values against time with results as follows: In the group treated solely with medication, both vital capacity and forced expiratory volume (VC and FEV1) dropped in a statistically significant manner over the 2-year period with \( p < 0.05 \) and \( r = -0.72/-0.91 \). In the group with additional physiotherapy, both vital capacity and forced expiratory volume (VC and FEV1) showed a statistically insignificant drop with \( r = -0.17/-0.04 \). Also in the physiotherapy group, the relative thoracic gas volume dropped in a statistically significant manner with \( r = -0.9 \), whereas in the medication-only group a rising tendency was observed that did not reach a statistically significant level at \( r = +0.61 \). The correlation of airway resistance figures throughout this period did not provide any statistically significant results.

The means for the two groups were then subjected to both the Wilcoxon test and the sign test. For vital capacity a statistically significant drop was determined in the medication-only group compared with the physiotherapy group. Thoracic gas volume decreased in the physiotherapy group more than in the medication-only group by a statistically significant margin. Airway resistance was also reduced in the physiotherapy group by a statistically significant amount compared with the medication-only group. No difference was registered in these tests for force expiratory volume (Tab. 3).

Figs. 5 and 6 show the correlation of the mean values for FEV and thoracic gas volume during the test period, whereby "w/o Corn" means without RC-Cornet® and "w Corn" means with RC-Cornet®.

The diagrams show less FEV1 drop in the physiotherapy group over the 2-year period compared with the medication-only group and at the same time a drop in TGV in the physiotherapy group in contrast to a rise in the medication-only group.

![Fig. 4](image1.png) Mean vital capacity in % of standard at various measurement time points. a Drug therapy. b Drug therapy plus physiotherapy with RC-Cornet®.

![Fig. 5](image2.png) Correlation of mean thoracic gas volume in % of standard with time (Time 1 = initial measurement, Time 2 = measurement after 3 months, etc). a Drug therapy. b Drug therapy plus physiotherapy with RC-Cornet®.

![Tab. 3](image3.png) Comparative development of mean pulmonary function data values in the two therapeutic groups

<table>
<thead>
<tr>
<th></th>
<th>Medication only</th>
<th>Medication plus RC-Cornet®</th>
<th>Wilcoxon test</th>
<th>Sign test</th>
</tr>
</thead>
<tbody>
<tr>
<td>VC % of standard</td>
<td>↓</td>
<td>p = 0.02</td>
<td>p = 0.02</td>
<td></td>
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<tr>
<td>Raw</td>
<td></td>
<td>p = 0.02</td>
<td>p = 0.02</td>
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<tr>
<td>TGV % of standard</td>
<td>↓</td>
<td>p = 0.01</td>
<td>p = 0.01</td>
<td></td>
</tr>
<tr>
<td>FEV1 % of standard</td>
<td>−</td>
<td>p = 0.09</td>
<td>p = 0.13</td>
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Hospitalizations
In the group treated with medication plus RC-Cornet®, 5 patients were put under inpatient care during the 2-year period due to exacerbations of their chronic obstructive bronchitis. 12 patients were hospitalized in the group not receiving physiotherapy.

Using the chi-square test, this results in a statistically significant difference with \( p < 0.001 \).

Time in hospital
The amount of time spent as inpatients was 18.3 ± 4.7 days in the medication-only group and 16.2 ± 6.3 days in the group that also received respiratory physiotherapy. The difference is not statistically significant.

Antibiotics consumption
Statistically significant differences were also determined in evaluation of how many patients required antibiotic treatment once or several times within the framework of outpatient therapy for exacerbations of COPD:

In the group receiving additional physiotherapy, 13 patients required antibiotics, in the group receiving medication only, the figure was 24 patients. The chi-square test result for these data is \( p < 0.0004 \).

Discussion
The present study demonstrated that the efficacy of the medication therapy currently recommended for COPD was significantly improved over the longer term by "combined PEP" physiotherapy. Thus the short-term positive effects of use of the RC-Cornet® observed earlier for COPD [4, 14] were not only confirmed for long-term therapy; it was also seen that the positive effects on pulmonary function and clinical treatments (hospitalization, antibiotics consumption) improved further the longer the physiotherapy was continued.

Oscillating PEP therapy dilates the bronchi. The oscillations also shear the mucus from the bronchial walls and reduce mucus viscosity [10, 15, 17]. Long-term PEP also improves collateral ventilation through the canals of Martin and Lambert and the pores of Kohn.

This renews entry of air into regions that are collapsed or filled with bronchial mucus, thus reducing residual volume [11, 12, 18]. Combined PEP also activates the surfactant with its oscillations, resulting in a stabilization of the bronchioloalveolar system [19].

The improvement of total clearance in the bronchial tree is also a likely contributor to the reduction of infection frequency and the lower frequency of hospitalization among the patients receiving the physiotherapy. The reduction of airway resistance and the decrease in hyperdistension (reduction of residual volume) also reduce the pulmonalis pressure least in theory. Oscillating PEP systems have a dyspnoea-reducing effect due to the vibrations generated in the mouth, throat and thorax [4]. As demonstrated in studies by Homma et al., a dyspnoea-reducing effect on the thorax is achieved in particular with mid-frequency oscillations between 80 and 120 Hz [20]. These oscillation frequencies simulate a higher rate of respiratory airflow to the sensors of the thoracic ligament and musculature apparatus and the sensors of the bronchial tree, which is experienced as decreased dyspnoea [10].

The reduction of dyspnoea and the ability to cough out mucus that would otherwise result in frustrated expectorant coughing due to the instability of the tracheobronchial system is likely to be one of the reasons why a high level of compliance was observed with physiotherapy of the RC-Cornet® in COPD patients. The results of this study underline the efficacy of rehabilitative measures in the form of combined PEP respiratory therapy as a beneficial supplement to drug therapy [5-7].

Fig. 6 Correlation of mean forced expiratory volume in % of standard with time (Time 1 = initial measurement, Time 2 = measurement after 3 months, etc). a Drug therapy. b Drug therapy plus physiotherapy with RC-Cornet®.
References

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