# RC-Cornet® PLUS Family

## Studienübersicht /
## Selected Study Summary

CEGLA
MEDIZINTECHNIK

Die OPEP Therapie ist seit den späten 90igern bekannt. Es gibt auf diesem Feld einige Weiterentwicklungen. Bitte finden Sie hier einen Auszug der entsprechend relevanten Literatur untergliedert in folgende Punkte:

OPEP studies are popular since the late 90th. From then many of further developments are published. Please, find in this study summary a selection of different topics related literature divided in three parts:

**Inhalt / Table of content**

***1.*** **Die Schleimproblematik bei Atemwegserkrankungen /** ***The mucus accumulation due to respiratory diseases*** **..... 3**

***2.*** **Studien, die OPEP-Therapien untersucht haben /** ***A selection of OPEP studies*** **..... 6**

**3. Leitlinien und deren Updates /** ***Guidelines and Updates*** **..... 22**

**4. RC-Cornet® N / RC-Cornet® PLUS NASAL..... 25**

**5. RC-Cornet® Tracheoset / RC-Cornet® PLUS TRACHEO..... 35**

**6. Impressum /** ***Imprint*** **..... 37**

# *1.* Die Schleimproblematik bei Atemwegserkrankungen / *The mucus accumulation due to respiratory diseases*

| **Titel** | **Clinical issues of mucus accumulation in COPD** |
|---|---|
| **Autor/Author** | FL Ramos; JS Krahnke; V. Kim |
| **Journal** | International Journal COPD 2014; 9: 139–150; Published online 2014 Jan 24. doi: 10.2147/COPD.S38938 |
| **Abstrakt/ Abstract** | Airway mucus is part of the lung's native immune function that traps particulates and microorganisms, enabling their clearance from the lung by ciliary transport and cough. Mucus hypersecretion and chronic productive cough are the features of the chronic bronchitis and chronic obstructive pulmonary disease (COPD). Overproduction and hypersecretion by goblet cells and the decreased elimination of mucus are the primary mechanisms responsible for excessive mucus in chronic bronchitis. Mucus accumulation in COPD patients affects several important outcomes such as lung function, health-related quality of life, COPD exacerbations, hospitalizations, and mortality. Nonpharmacologic options for the treatment of mucus accumulation in COPD are smoking cessation and physical measures used to promote mucus clearance. Pharmacologic therapies include expectorants, mucolytics, methylxanthines, beta-adrenergic receptor agonists, anticholinergics, glucocorticoids, phosphodiesterase-4 inhibitors, antioxidants, and antibiotics. |

| **Titel** | **Airway Clearance Techniques for Chronic Obstructive Pulmonary Disease** |
|---|---|
| **Autor/Author** | Osadnik CR; McDonald CF; Jones AP; Holland AE |
| **Journal** | Cochrane Database Syst Rev. 2012 Mar 14;(3):CD008328. doi: 10.1002/14651858.CD008328.pub2. |
| **Abstrakt/ Abstract** | Twenty-eight studies on 907 participants were included in the review. Study sample size was generally small (range 5 to 96 people) and overall quality was generally poor due to inadequate blinding and allocation procedures. Meta-analyses were limited by heterogeneity of outcome measurement and inadequate reporting of data.In people experiencing AECOPD, ACT use was associated with small but significant short-term reductions in the need for increased ventilatory assistance (odds ratio (OR) 0.21, 95% confidence interval (CI) 0.05 to 0.85; data from four studies on 171 people), the duration of ventilatory assistance (mean difference (MD) -2.05 days, 95% CI -2.60 to -1.51; mean duration for control groups seven days; data from two studies on 54 people) and hospital length of stay (MD -0.75 days, 95% CI -1.38 to -0.11; mean duration for control groups nine days; one study on 35 people). Data from a limited number of studies revealed no significant long-term benefits of ACTs on the number of exacerbations or hospitalisations, nor any short-term beneficial effect on health-related quality of life (HRQoL) as measured by the |

| | |
|---|---|
| | St. George's Respiratory Questionnaire (SGRQ) total score (MD -2.30, 95% CI -11.80 to 7.20; one study on 59 people).In people with stable COPD, data from single studies revealed no significant short-term benefit of ACTs on the number of people with exacerbations (OR 3.21, 95% CI 0.12 to 85.20; one study on 30 people), significant short-term improvements in HRQoL as measured by the SGRQ total score (MD -6.10, 95% CI -8.93 to -3.27; one study on 15 people) and a reduced long-term need for respiratory-related hospitalisation (OR 0.27, 95% CI 0.08 to 0.95; one study on 35 participants).The magnitude of effect of PEP-based ACTs on the need for increased ventilatory assistance and hospital length of stay was greater than for non-PEP ACTs, however we found no statistically significant subgroup differences. There was one report of vomiting during treatment with postural drainage and head-down tilt.glucocorticoids, phosphodiesterase-4 inhibitors, antioxidants, and antibiotics. |

| **Titel** | **Airway Mucus Function and Dysfunction** |
|---|---|
| **Autor/Author** | John V. Fahy, M.D., and Burton F. Dickey, M.D. |
| **Journal** | N Engl J Med. 2010 Dec 2;363(23):2233-47. doi: 10.1056/NEJMra0910061 |
| **Abstrakt/ Abstract** | The lungs are remarkably resistant to environmental injury, despite continuous exposure to pathogens, particles, and toxic chemicals in inhaled air. Their resistance depends on a highly effective defense provided by airway mucus, an extracellular gel in which water and mucins (heavily glycosylated proteins) are the most important components. Airway mucus traps inhaled toxins and transports them out of the lungs by means of ciliary beating and cough. Paradoxically, although a deficient mucous barrier leaves the lungs vulnerable to injury, excessive mucus or impaired clearance contributes to the pathogenesis of all the common airway diseases. This review examines the normal formation and clearance of airway mucus, the formation of pathologic mucus, the failure of mucus clearance that results in symptoms and abnormal lung function, and the therapy of mucus dysfunction. |

| **Titel** | **Revisited Role for Mucus Hypersecretion in the Pathogenesis of COPD** |
|---|---|
| **Autor/Author** | John V. Fahy, M.D., and Burton F. Dickey, M.D. |
| **Journal** | Eur Respir Rev. 2010 Jun;19(116):109-12. doi: 10.1183/09059180.00002710. |
| **Abstrakt/ Abstract** | Chronic obstructive pulmonary disease (COPD) is a heterogeneous and complex disease of which the basic pathophysiological mechanisms remain largely unknown. On the basis of recent results from pathological studies and large clinical trials, the presence of airway inflammation does not seem to be sufficient to explain the complexity of the disease and the |

| | |
|---|---|
| | relatively poor response to treatment. It is probably time to abandon the concept of COPD as a unique disease and define, identify and treat the various aspects, which may differ between individuals. Among the different phenotypic distinctions, the classical distinction "chronic bronchitis" has mucus hypersecretion as the key presenting symptom. Its role in COPD has been the subject of an ongoing debate; however, it now appears to be being re-evaluated due to findings from recent epidemiological and pathological studies. In this context, the view that chronic mucus hypersecretion plays a secondary role in the pathogenesis of COPD should be abandoned and instead, drugs targeting mucus hypersecretion should be considered as a treatment option. |

| **Titel** | **Mucus hypersecretion in COPD: should we only rely on symptoms?** |
|---|---|
| **Autor/Author** | Burgel PR, Martin C. |
| **Journal** | Eur Respir Rev. 2010 Jun;19(116):109-12. doi: 10.1183/09059180.00002710. |
| **Abstrakt/ Abstract** | In the present issue of the European Respiratory Review, Cerveri and Brusasco propose that “the view that chronic mucus hypersecretion plays a secondary role in the pathogenesis of COPD should be abandoned and instead, mucolytic agents should be considered as a treatment option”. In the same series, Balsamo et al. provide an overview of currently available mucoactive drugs, and Decramer and Janssens examine the evidence for proposing long-term treatment with so-called “mucolytics” (e.g. N-acetylcysteine and carbocysteine) in patients with chronic obstructive pulmonary disease (COPD). |

| **Titel** | **Exacerbations of Chronic Obstructive Pulmonary Disease and Chronic Mucus** |
|---|---|
| **Autor/Author** | Wedzicha JA, Donaldson GC |
| **Journal** | Respir Care. 2003 Dec;48(12):1204-13; discussion 1213-5. |
| **Abstrakt/ Abstract** | Exacerbations of chronic obstructive pulmonary disease (COPD) cause morbidity, hospital admissions, and mortality, and strongly influence health-related quality of life. Some patients are prone to frequent exacerbations, which are associated with considerable physiologic deterioration and increased airway inflammation. About half of COPD exacerbations are caused or triggered primarily by bacterial and viral infections (colds, especially from rhinovirus), but air pollution can contribute to the beginning of an exacerbation. Type 1 exacerbations involve increased dyspnea, sputum volume, and sputum purulence; Type 2 exacerbations involve any two of the latter symptoms, and Type 3 exacerbations involve one of those symptoms combined with cough, wheeze, or |

| | |
|---|---|
| | symptoms of an upper respiratory tract infection. Exacerbations are more common than previously believed (2.5-3 exacerbations per year); many exacerbations are treated in the community and not associated with hospital admission. We found that about half of exacerbations were unreported by the patients, despite considerable encouragement to do so, and, instead, were only diagnosed from patients' diary cards. COPD patients are accustomed to frequent symptom changes, and this may explain their tendency to underreport exacerbations. COPD patients tend to be anxious and depressed about the disease and some might not seek treatment. At the beginning of an exacerbation physiologic changes such as decreases in peak flow and forced expiratory volume in the first second (FEV(1)) are usually small and therefore are not useful in predicting exacerbations, but larger decreases in peak flow are associated with dyspnea and the presence of symptomatic upper-respiratory viral infection. More pronounced physiologic changes during exacerbation are related to longer exacerbation recovery time. Dyspnea, common colds, sore throat, and cough increase significantly during prodrome, indicating that respiratory viruses are important exacerbation triggers. However, the prodrome is relatively short and not useful in predicting onset. As colds are associated with longer and more severe exacerbations, a COPD patient who develops a cold should be considered for early therapy. Physiologic recovery after an exacerbation is often incomplete, which decreases health-related quality of life and resistance to future exacerbations, so it is important to identify COPD patients who suffer frequent exacerbations and to convince them to take precautions to minimize the risk of colds and other exacerbation triggers. |

## *2.* Studien, die OPEP-Therapien untersucht haben / *A selection of OPEP studies*

| **Titel** | **Oscillatory Positive Expiratory Pressure on Respiratory Resistance in Chronic Obstructive Pulmonary Disease With a Small Amount of Secretion A Randomized Clinical Trial** |
|---|---|
| **Autor/Author** | Gastaldi AC1, Paredi P, Talwar A, Meah S, Barnes PJ, Usmani OS |
| **Journal** | Medicine (Baltimore). 2015 Oct;94(42):e1845. doi: 10.1097/MD.0000000000001845 |
| **Abstrakt/ Abstract** | This study aims to evaluate the acute effects of an oscillating positive expiratory pressure device (flutter) on airways resistance in patients with chronic obstructive pulmonary disease (COPD).Randomized crossover study: 15 COPD outpatients from Asthma Lab-Royal Brompton Hospital underwent spirometry, |

| | |
|---|---|
| | impulse oscillometry (IOS) for respiratory resistance (R) and reactance (X), and fraction exhaled nitric oxide (FeNO) measures.Thirty minutes of flutter exercises: a "flutter-sham" procedure was used as a control, and airway responses after a short-acting bronchodilator were also assessed.Respiratory system resistance (R): in COPD patients an increase in X5insp (-0.21 to -0.33 kPa/L/s) and Fres (24.95 to 26.16 Hz) occurred immediately after flutter exercises without bronchodilator. Following 20 min of rest, a decrease in the R5, ΔR5, R20, X5, and Ax was observed, with R5, R20, and X5 values lower than baseline, with a moderate effect size; there were no changes in FeNO levels or spirometry.The use of flutter can decrease the respiratory system resistance and reactance and expiratory flow limitation in stable COPD patients with small amounts of secretions. |

| **Titel** | **Oscillating Positive Expiratory Pressure Therapy in Chronic Obstructive Pulmonary Disease and Bronchiectasis** |
|---|---|
| **Autor/Author** | S. Svenningsen, G. Paulin, A. Wheatley, D. Pike, J. Suggett, D. McCormack, G. Parraga |
| **Journal** | European Respiratory Journal 2014 44: P3679 |
| **Abstrakt/ Abstract** | RATIONALE: Airway clearance methods such as oscillating positive expiratory pressure (oPEP) are proposed to provide benefit in patients with chronic obstructive pulmonary disease (COPD) and bronchiectasis by mobilizing secretions and enhancing mucous movement.<br>METHODS: A six-week cross-over study was completed in 29 subjects (n=15 COPD, n=14 bronchiectasis) who provided written informed consent and were randomized to oPEP therapy (Aerobika®, Trudell Medical International) four-times daily. Pulmonary function tests, the Six Minute Walk distance (6MWD), St George's Respiratory Questionnaire (SGRQ) and the Patient Evaluation Questionnaire (PEQ) were used to evaluate therapy effects.<br>RESULTS: There were no adverse events related to oPEP use. There were statistically significant improvements in 6MWD (p=0.01), SGRQ total score (p=0.01), and the PEQ Cough Frequency (p=0.006), dyspnea (p=0.03) and ease in bringing up sputum (p<0.0001).<br>CONCLUSIONS: In subjects with COPD and bronchiectasis, three weeks of oPEP therapy (Aerobika®) was well-tolerated and there was improved dyspnea, quality of life, exercise capacity and ease in bringing up sputum. |

| **Titel** | **COMPARISON OF TWO OSCILLATING POSITIVE EXPIRATORY PRESSUREDEVICES: ACAPELLA VERSUS RC CORNET** |
|---|---|

| | |
|---|---|
| **Autor/Author** | Sherry Babic, Robert L. Chatburn; Respiratory Institute, Cleveland Clinic, Cleveland, OH |
| **Journal** | Respiratory Care; October 2013; Vol. 58; No. 10; page 1724 |
| **Abstrakt/ Abstract** | The Acapella and the RC Cornet are devices that combine oscillations and positive expiratory pressure (PEP) for secretion removal. We hypothesized that these devices would produce similar pressure and flow waveforms. |

| **Titel** | **Physiotherapy treatment in cystic fibrosis: airway clearance techniques** |
|---|---|
| **Autor/Author** | S. Ammani Prasad, MCSP, Tamara Orska, MCSP, Kate Ferguson, MCSP, Penny Agent, MCSP and Mary Dodd, FCSP on behalf of the Association of Chartered Physiotherapists in Cystic Fibrosis. Updated by Elaine Dhouieb MCSP and Alison Gates MCSP. |
| **Journal** | Cystic Fibrosis our focus, 2011, S.9-10 |
| **Abstrakt/ Abstract** | "The RC-Cornet® consists of a curved hard plastic tube within which sits a soft flexible rubber tube. It works in a very similar way as the flutter, producing a vibration and PEP effect in the airways. The degree of PEP and vibration can be altered by changing the twist in the rubber tube. ƒThe RC-Cornet®t can be used in any treatment position and like the flutter a combination of breathing techniques are used to help to move and clear secretions". |

| **Titel** | **COMPARISON OF ACAPELLA AND RC-CORNET FOR AIRWAY CLEARANCE IN BRONCHIECTASIS-A PILOT STUDY** |
|---|---|
| **Autor/Author** | Shabari, V Prem, Gopala Krishna Alaparthi, Vaishali, Vishak acharya |
| **Journal** | IJCRR, ISSN 0975-5241, IC Value of Journal: 4.18, “Let the science be your passion”, Vol 3 / Issue 11 / Nov 2011 |
| **Abstrakt/ Abstract** | Background: Rc-cornet is a hand held PEP device used in facilitating airway clearance.<br>Acapella is also a PEP device already known to be effective in airway clearance. Objective:<br>The objective of the study was to compare Acapella and Rc-cornet device as airway clearanc in bronchiectasis subjects and to determine patient preference between the two devices.<br>Method: Forty patients (20 male and 20female) mean age 52.20 ± 15.66 with history of<br>expectoration of more than 30ml sputum per day were recruited. The sequence of the therapy was allocated by block randomization. Assessment and familiarization session was performed on day 1. Treatment employing the Acapella and Rc-cornet were done on days 2 and 3 Treatment order and allocation was determined by block randomization. Sputum volume was measured during and 2hours after the treatment and patient |

| | |
|---|---|
| | treatment preference was recorded. Results: A statistically significant difference was found in the sputum volume expectorated with Rc-cornet (36.58 ± 7.21) compared with Acapella (34.63±9.03). Patients preferred Rccornet in terms of clearing secretions. Conclusion: The present study proved there was increased sputum clearance following the use of Rc-cornet when compared to Acapella. In addition Rc-cornet was preferred by patients who judged that it was more useful in clearing secretions. |

| **Titel** | **Beyond postural drainage and percussion: Airway clearance in peoble with cystic fibrosis** |
|---|---|
| **Autor/Author** | J.A. Pryor, E. Tannenbaum, S.F.Scott, J. Burgess, D. Cramer, K. Gyi, M.E. Hodson |
| **Journal** | Journal of cystic fibrosis 9 (2010), 187-192 |
| **Abstrakt/ Abstract** | BACKGROUND: Evidence indicates that there are no statistically significant differences in effectiveness among the airway clearance techniques (ACTs) of active cycle of breathing, autogenic drainage, positive expiratory pressure (PEP) or oscillating PEP in the short-term, but are there differences in the long-term (one year)? The objective of the study was to demonstrate non-inferiority in the long-term. METHODS: Seventy-five people with cystic fibrosis entered the prospective, randomised controlled trial of these five different ACTs. The primary outcome measure was forced expiratory volume in one second (FEV(1)). Secondary outcome measures included exercise capacity and health related quality of life. RESULTS: Using intention to treat, data were available on 65 subjects at the end of the study period. There were no statistically significant differences among the regimens in the primary outcome measurement of FEV(1) (p=0.35). CONCLUSION: In different countries either one or several airway clearance regimens are used. This study provides evidence in support of current practices. Cornet were done on days 2 and 3 Treatment order and allocation was determined by block randomization. Sputum volume was measured during and 2hours after the treatment and patient treatment preference was recorded. Results: A statistically significant difference was found in the sputum volume expectorated with Rc-cornet (36.58 ± 7.21) compared with Acapella (34.63±9.03). Patients preferred Rccornet in terms of clearing secretions. Conclusion: The present study proved there was increased sputum clearance following the use of Rc-cornet when compared to Acapella. In addition Rc-cornet was preferred by patients who judged that it was more useful in clearing secretions. |

| **Titel** | **Ist Atemphysiotherapie evidenzbasierte Therapie? (only in German language available)** |
|---|---|
| **Autor/Author** | U.H. Cegla |

| | |
|---|---|
| **Journal** | Atemwegs- und Lungenkrankheiten, Jahrgang 36, NR. 5/2010, S.205-216 |
| **Abstrakt/ Abstract** | Von der heutigen Therapie wird verlangt, dass sie evidenzbasiert ist, das heißt ihre Wirksamkeit muss durch klinische Studien, die festgelegten statistischen Anforderungen genügen, bewiesen sein. Für die oszillierenden PEP-Geräte (Flutter, RC-Cornet® und Acapella) ist diese “Wirksamkeit” bewiesen. Die einzelnen Geräte zeigen bei unterschiedlicher Einstellung bzw. Neigung (Flutter) bei gleich großem Atemdruck unterschiedliche Flüsse und Frequenzen. Darüber hinaus ist bei den einzelnen Geräten je nach Einstellung auch der entstehende positive Ausatemdruck (PEP) im Sinne eines dauerpositiven Drucks, wie bei der PEP-Maske (statischer PEP), bzw. kombinierter PEP (Dauer positiver Druck mit aufgesetzten Druckschwankungen) oder dynamischer PEP (der Druck steigt von Null auf ein Maximum und fällt auf Null zurück) zu erreichen. Auch das zeitliche Verhalten des PEP-Anstiegs kann durch die Geräteeinstellungen beeinflusst werden (symmetrischer PEP, meist in Form einer Sinusschwingung, und asymmetrischer PEP, bei dem der Druck langsam ansteigt, um dann abrupt abzufallen). Das Druck- und Frequenzverhalten der einzelnen oszillierenden PEP-Geräte bei steigendem Druck wurde untersucht. Bei Normalpersonen wurde an den oszillierenden PEP-Geräten in verschiedenen Einstellungen der als “angenehm empfundene Druck” ermittelt; dieser lag deutlich höher (etwa ein Drittel) als bei einer Gruppe von 50 obstruktiven Patienten, bei denen der jeweils aufgebrachte Druck beim Blasen in die verschiedenen Einstellungen des RC-Cornet® gemessen wurde. Anhand der entstehenden unterschiedlichen PEP-Druck-Formen werden Vorschläge zur Einstellung der Geräte zur Therapie unterschiedlicher Störungen gemacht. Die Durchsicht der bestehenden Literatur zeigt, dass die Therapie mit oszillierenden PEP-Geräten evidenzbasiert ist. |

| | |
|---|---|
| **Titel** | **Influence that oscillating positive expiratory pressure using predetermined expiratory pressures has on the viscosity and transportability of sputum in patients with bronchiectasis** |
| **Autor/Author** | Ramos EM1, Ramos D, Iyomasa DM, Moreira GL, Melegati KC, Vanderlei LC, Jardim JR, Oliveira AS |
| **Journal** | J Bras Pneumol. 2009 Dec;35(12):1190-7 |
| **Abstrakt/ Abstract** | OBJECTIVE: To determine the effectiveness of oscillating positive expiratory pressure (OPEP) using predetermined expiratory pressures on the viscosity and transportability of sputum in patients with bronchiectasis. METHODS: The study involved 15 stable patients with bronchiectasis (7 males; mean age = 53 +/- 16 years), submitted to two consecutive OPEP interventions, with a 24-h interval between the two, using positive expiratory pressures set at 15 cmH2O (P15) and 25 cmH2O (P25). The protocol consisted of a voluntary cough; another voluntary cough 20 min later, designated time zero (T0); a 10-min rest period; and two 10-min series (S1 and S2, using OPEP at P15 and P25 in both), with |

| | |
|---|---|
| | a 10-min interval between the two. The viscosity and transportability of sputum were evaluated by viscometry, relative transport velocity on frog palate, transport in a simulated cough machine and contact angle. Sputum samples were collected at T0, after S1 and after S2. Specific statistical tests were performed depending on the type of data distribution. RESULTS: In comparison with the values obtained at T0, sputum viscosity decreased significantly after S1 at P15 and after S2 at P25. There were no significant differences among all of the samples in terms of transportability. CONCLUSIONS: The fact that sputum viscosity decreased whether OPEP was performed at P15 or at P25 suggests that there is no need to generate high expiratory pressure to achieve the desired result. |

| **Titel** | **Ambulante Physiotherapie bei Patienten mit COPD**<br>***Out patient physiotherapy for COPD sufferers*** |
|---|---|
| **Autor/Author** | S. Weise, D. Pfeiffer-Kascha |
| **Journal** | Atemwegs-und Lungenkrankheiten, 2008, Dustri-Verlag, Jahrgang 24 (33-42) |
| **Abstrakt/ Abstract** | Ambulante Physiotherapie bei Patienten mit COPD<br>Ziel physiotherapeutischer Behandlungen ist es, zur Ver besse rung der Lebensqualität dieser Patienten beizutragen. Betroffene lernen, ein einfaches Verständnis der Pathomechanismen zu entwickeln und ihren Zustand mit Hilfe eines individuell abgestimmten Selbsthilfe-programms zu stabilisieren und so vorhersehbaren Fehlentwicklungen von Lunge und Atempumpe rechtzeitig entgegen zu wir ken. Durch Selbsthilfetechniken lernen Patienten, die Atemwege in Ruhe und unter körperlicher Belastung offen zu halten, Lungenüberblähung zu reduzieren, das Zwerchfell mobiler und kräftiger zu halten, die Atemwege effektiv und kraftsparend zu reinigen, so wie unproduktiven Reizhusten zu dämpfen. Auf diese Weise können die Atemnot reduziert und eine Verbesserung der allgemeinen körperlichen Leistungsfähigkeit erzielt werden. (...) Zur Entblähung der Lunge werden Techniken zum Offenhalten der Atemwege bei forcierter Ausatmung eingesetzt. Diese PEP-Techniken (positive expiratory pressure technique) werden mit körpereigenen Stenosen und Fremdstenosen geschult. Zur Selbsthilfe wird der Einsatz der dosierten Lippenbremse in Ruhe und in modifizierter Form unter Belastung vermittelt. In Länge und Durchmesser individuellangepasste Strohhalmstücke haben sich im Alltag als exspiratorische Stenose sehr bewährt. Bei Bedarf werden Patienten mit PEP-Geräten vertraut gemacht, beispielsweise Pari-PEPSystem® und BA-Tube als auch mit oszillierenden PEP-Geräten wie VRP1® Flutter, RC-Cornet®, Acapella®.<br><br>*Physiotherapy for COPD sufferers is aimed at in creasing their quality of life. Patients should develop a simple under standing of the pathological mechanisms under lying COPD and learn to stabilise their condition through a selfmanagement program* |

| | |
|---|---|
| | *tailored to their individual needs, which counteracts predictable maladaptations of the lung and ventilatory pump. Self-management techniques reduce pulmonary hyper inflation, maintain strength and mobility of the diaphragm, allow efficient and energy conserving clearance of the airways, ameliorate non productive dry coughes and enable patients to keep their airways open both at rest and during physical activity. This helps to reduce dispnoea and to increase physical stamina.* |

| | |
|---|---|
| **Titel** | **Krankheitsverlauf bei schwerer COPD mit und ohne Physiotherapie mit dem RC-Cornet®. Eine randomisierte 2-Jahres-Langzeitstudie**<br><br>***Course of Severe COPD with and without Physiotherapy with the RC-Cornet®A Randomized 2 Years Long-term study*** |
| **Autor/Author** | U.H. Cegla, J.-H. Jost, A. Harten, T. Weber, S. Wissmann |
| **Journal** | Pneumolie Sonderdruck, 2002, Jahrgang 56, S. 418-424 |
| **Abstrakt/ Abstract** | Einleitung: Die Effektivität einer Atemphysiotherapie mit combined-PEP (RC-Cornet® Ausgangsposition) in der Langzeittherapie wurde im folgenden Setup untersucht. Studiendesign: Randomisierte prospektive Studie über 2 Jahre an 50 Patienten mit schwerer COPD (12 w, 38 m, Alter 63,1 Jahre, FEV1 41 %, DLCO 51 % des Solls). Die Patienten waren zu Beginn der Studie infektfrei und Exraucher. Die erste Gruppe wurde nur medikamentös therapiert (Theophyllin, Salmeterol, Ipratropiumbromid, Glucocorticosteroide systemisch 5 mg Prednisolonäquivalent). Die zweite Gruppe erhielt die Medikation wie bei Gruppe 1 plus Physiotherapie 3 × täglich mindestens über 5 Minuten und falls erforderlich öfter mit dem RC-Cornet® in Ausgangsstellung (erzeugt einen combined PEP, d. h., Dauer-PEP plus aufgesetzte Druckoszillationen). In 3- bzw. im zweiten Jahr in 4-monatigem Abstand erfolgten Lungenfunktionskontrollen und klinische Untersuchungen. Die Compliance wurde mittels Theophyllin- und Cortisolspiegel-Kontrollen, Inspektion des RC-Cornets® sowie Befragung der Patienten überprüft. Ergebnisse: In der zusätzlich mit dem RC-Cornet® behandelten Gruppe sank das TGV und der Atemwegswiderstand im Vergleich zur nur medikamentösen Gruppe signifikant mit $p < 0,0177$ bzw. $p < 0,0179$ ab. In dieser Gruppe stieg auch die Vitalkapazität mit $p < 0,0179$ signifikant gegenüber der nur medikamentös behandelten Gruppe an. In der nur medikamentös behandelten Gruppe benötigten 24 der 25 Patienten Antibiotika, in der Gruppe, die zusätzlich mit dem RC-Cornet® behandelt wurden, waren dies 13 Patienten (Chi-Quadrat $p < 0,0004$). Auch die Notwendigkeit der Krankenhauseinweisungen unterschied sich in beiden Gruppen signifikant: 5 stationäre Behandlungen in der RC-Cornet®-Gruppe und 12 in der rein medikamentösen Gruppe, $p < 0,001$. Die Dauer des Krankenhausaufenthaltes unterschied sich nicht signifikant und betrug 18,3 ± 4,7 Tage in der medikamentösen Gruppe und |

| | |
|---|---|
| | 16,2 ± 6,3 Tage in der RC-Cornet®-Gruppe. Schlussfolgerung: Die Studie zeigt, dass die medikamentöse Therapie der COPD durch eine Langzeit-Atemphysiotherapie mit combined-PEP (RC-Cornet® in der Ausgangsposition) erfolgreich und ökonomisch ergänzt wird.<br><br>*The efficacy of respiratory physiotherapy by combined-PEP (RC-Cornet® in combined-PEP-position) was evaluated in a long-term study with the following set up. Study design: Randomized prospective clinical trial over 2 years in 50 patients with severe COPD (12 f, 38 m, 63,1 y, FEV1 41 %, DLCO 51 % of the normal). Patients were without infection and exsmokers at begin of the trial. One group was treated only by drug therapy (theophylline, salmeterol, ipratropiumbromide, systemic steroids 5 mg prednisolone equivalent). The second group received the same drug therapy plus physical therapy with the RC-Cornet® (oscillating PEP; in combined PEP-position) 3 times daily at least for 5 minutes or whenever needed. Lung function data were controlled every 3 month during first year and every 4 month in the second year. The compliance was checked by theophylline and cortisol blood levels, inspection of the functionality of the RC-Cornet® and by questioning the patient about compliance with the therapy. Results: TGV (% of normal) and airway resistance (measured by bodyplethysmography) decreased significantly in contrast to the "mere" drug therapy ($p < 0.0177$, $p < 0.0179$). VC (% of normal) increased significant $p < 0.0179$ in the RC-Cornet® therapy group. In this group significantly less patients (13/24) needed antibiotics in comparison to the "mere" drug group (Chi-Quadrat $p < 0.0004$). Also the need for hospital care was significantly less in the RC-Cornet® group (5/12) in comparison to the drug therapy group (Chi-Quadrat < 0.000765). The length of hospital stay in the two groups was not significantly different: 16.2 ± 6.3 days in the RC-Cornet®-group and 18.3 ± 4.7 days in the drug therapy-group. Conclusion: This study proves the efficacy of respiratory physiotherapy with combined-PEP in addition to drug therapy in the management of COPD-patients.* |

| **Titel** | **RC-Cornet® verbessert den Effekt einer Inhalationstherapie mit Ipratropiumbromid (Atrovent®) bei COPD Patienten**<br><br>***RC-Cornet® Improves the Bronchodilaing Effect of Ipratropium-bromide (Atrovent®) inhalation in COPD patients*** |
|---|---|
| **Autor/Author** | U.H. Cegla, J.-H. Jost, A. Harten, T. Weber |
| **Journal** | Pneumologie 2001, Jahrgang 55, S.465-469 |
| **Abstrakt/ Abstract** | 35 Patienten mit schwerer COPD und tracheobronchialer Instabilität wurden prospektiv, randomisiert, cross-over an 2 aufeinander folgenden Tagen zunächst bezüglich Änderung der Lungenfunktion (Bodyplethysmographie) 20 Minuten nach Salbutamol- (Salbulair® Autohaler) Inhalation untersucht. Danach erfolgte eine Inhalation von Ipratropiumbromid im Düsenvernebler |

| | |
|---|---|
| | (Pariboy mit LC-plus-Vernebler), wobei in der Gruppe A ein oszillierendes PEP-System (RC-Cornet® Position 1) in den Ausatemschenkel des Verneblers geschaltet war und in der Gruppe B eine herkömmliche Inhalation mit Ipratropiumbromid erfolgte. In der Gruppe A (mit oszillierendem positiven Ausatemdruck) war die ipratropiumbromidbedingte Verbesserung der Lungenfunktion statistisch signifikant besser als in der Gruppe B, die konventionell Ipratropiumbromid inhalierte (Atemwegswiderstand-Abfall $p < 0,0002$, Vitalkapazität-Anstieg $p < 0,0051$, Sekundenkapazität-Anstieg $p < 0,0161$ - Wilcoxon-Test für gepaarte Stichproben). Außer der Verbesserung der Lungenfunktion verkürzt sich durch Kombination der Inhalation mit der gleichzeitigen Physiotherapie die „Therapiezeit" der Patienten.<br><br>*In 35 patients with severe COPD and tracheal-bronchial instability the bronchodilatory effect of salbutamol (Salbulair® Autohaler) was tested prospectively, randomized and crossover on two consecutive days by bodyplethysmography. Following the salbutamol inhalation, the effect of ipratropiumbromide inhalation (by Pariboy and LC-plus-nebulizer) was evaluated in group A with an oscillating PEP-system (RC-Cornet®, Position 1) in the expiratory outlet of the nebulizer and in group B with conventional inhalation by the Pari-system. The bronchodilatory effect was statistically significant better in group A inhaling ipratropiumbromide with the RC-Cornet® in the expiratory limb of the nebulizer in comparison to "normal" inhalation (decrease in airway resistance $p < 0.0002$, increase in vitacapacity $p < 0.0051$, increase in FEV1 $p < 0.0161$, Wilcoxon-Test for matched pairs). Using an oscillating PEP-system in the expiratory outlet of a nebulizer does not only increase the bronchodilatory effect of ipratropiumbromide but also shortens by combining inhalation and physiotherapy the time necessary for therapy in those patients.* |

| **Titel** | **Physikalische Therapie bei COPD - Evidence Based Medicine?**<br><br>***Physical Therapy in COPD - Evidence Based Medicine?*** |
|---|---|
| **Autor/Author** | SteierJ., Petro W. |
| **Journal** | Pneumologie 2002, Jahrgang 56, S.388-396 |
| **Abstrakt/ Abstract** | (...) Ein weiteres Prinzip zur Lockerung des intrabronchialen Schleims sind die exspiratorisch benutzten Geräte, die eine Oszillation der Luftsäule bei positivem intrabronchialen Druck bewirken. Die Absicht liegt darin, die Viskosität des Schleims, den Hustenreiz, Atemwegswiderstand und die Dyspnoe zu vermindern und das FEV1 zu erhöhen.<br>Es existieren zwei verschiedene Systeme: der sogenannte Flutter (VRP-1 Desitin) und das RC-Cornet®. Das RC-Cornet® bietet dabei Vorteile, da es lageunabhängig verwendet werden kann und sich daher auch zur physikalischen Anwendungen ( z.B. Lagerungsdrainage ) anbietet, während der Flutter aufgrund |

| | |
|---|---|
| | seiner inseitigen Kugel nur in senkrechter Haltung zu verwenden ist. Außerdem können beim RC-Cornet® verschiedene Positionen des Mundstücks voreingestellt werdendie eine Variation der erzeugten Druckform zwischen peak to zero und Dauer-PEP mit aufgesetzten Druckschwankungen ermöglichen. (...)<br><br>*Several therapeutical options of physical therapy in COPD show significant effects on the organism. Some of those effects are verified, but there is still an uncertainty about the exact influences on the disease and the beneficial outcome, especially because different trials describe contradictory results. Existing studies observed an improved respiratory mechanism with a more economical ventilatory work and a better gas exchange by use of physical therapy. Therefore the right indication for certain options of physical therapy should be defined, so that the outcome can be controlled and a benefit can be drawn from the effects. Sufficient data of existing trials for the whole physical therapy in COPD is still deficient. Due to an inappropriate study design and/or the number of observed patients a lot of clinical studies are not qualified to lead to significant results and recommenda-tions. For the future it is necessary to investigate the exact effects of physical therapy with controlled, randomised, clinical trials further on. Hereby an improvement of the care of patients with COPD can be achieved andthebeneficial effectsand theoutcome with physical therapy can better be estimated.* |

| **Titel** | **Physiotherapie mit oszillierenden PEP-Systemen (RC-Cornet® and VRP1®) bei COPD (only in German language available)** |
|---|---|
| **Autor/Author** | U.H. Cegla |
| **Journal** | Pneumologie 2000, Jahrgang 54, S.440-446 |
| **Abstrakt/ Abstract** | Zusammenfassung: Oszillierende PEP-Systeme kombinieren verschiedenste physiotherapeutische Ansätze miteinander. Anhand der unterschiedlichen physikalischen Prinzipien des RC-Cornet® und des VRP1 wird der differenzierte Einsatz dieser Systeme aufgrund der unterschiedlichen Druck- und Flusskinetiken bei COPD, Bronchiektasen, Mukoviszidose besprochen und durch klinische und In-vitro-Untersuchungen belegt. Dabei bietet das RC-Cornet® die Möglichkeit, von einem Dauer-PEP mit sehr geringen Druckschwankungen durch Drehen des Mundstückes auf maximale Druckschwankungen, wie sie beim VRP1 vorkommen, zu wechseln. Nennenswerte Unterschiede zwischen den beiden oszillierenden PEP-Systemen finden sich bei COPD ab einer Sekundenkapazität von unter 1,5l/s. Ferner wird beim RC-Cornet® die gesamte Ausatmung in Druck- und Flussschwankungen umgesetzt. Es ist damit effektiver |

| | |
|---|---|
| | als das Flutter, bei dem bei jeder Öffnung des Kugelventils erhebliche Mengen Luft im Bypass verloren gehen. |

| | |
|---|---|
| **Titel** | **Chronische Lungenerkrankungen - Therapien bei Asthma, chronisch obstruktiver Bronchitis und Mukoviszidose (only in German language available)** |
| **Autor/Author** | U.H. Cegla; H. Mitfessel; K. Kenn; H. Grasemann und F. Ratjen |
| **Journal** | Forschung und Praxis, Das Wissenschafts-Journal der Ärzte Zeitung, Nov. 2000, Jahrgang 19, Nr. 309 |
| **Abstrakt/ Abstract** | Mit der physikalischen Therapie soll das Abhusten des Schleims gefördert werden. Aufgrund des Lungenemphysems und der verminderten Retraktionskraft des Lungengewebes an den Bronchien haben sich hier vor allem oszillatorische PEP-Systeme, z.B. das RC-Cornet® bewährt. Beim Blasen durch dieses Gerät werden in den Bronchien Druck- und Flußschwankungen erzeugt, welche die Bronchialwände kurzfristig erweitern und so den Schleim von den Bronchialwänden abscheren, der dann mit der Ausatemluft nach außen abgegeben wird. Ein weiterer Effekt dieser oszillatorischen Therapie: die Lungenperipherie wird erweitert und über die Vibrationen im Kehlkopfbereich wird die Dyspnoe vermindert. Die physikalische Therapie, ebenso wie das Erlernen atemerleichternder Stellungen, sollten keinem COPD-Patienten vorenthalten werden. |

| | |
|---|---|
| **Titel** | **Physiotherapie bei Patienten mit COAD und tracheobronchialer Instabilität - Vergleich zweier oszillierender PEP-Systeme (RC-Cornet®, VRP1 Desitin)**<br><br>***Physical therapy in patients with COPD and tracheobronchial instability-comparison of 2 oscillating PEP systems (RC-Cornet, VRP1 Desitin). Results of a randommized prospective study of 90 patients*** |
| **Autor/Author** | U.H.Cegla, M. Bautz, G. Fröde, Th. Werner |
| **Journal** | Pneumologie 1997, Jahrgang 51, S. 129-136 |
| **Abstrakt/ Abstract** | In einer randomisierten Prospektivstudie an 90 Patienten mit COAD und tracheobronchialer Instabilität wurden 3 Therapiegruppen gebildet. Gruppe 1: Therapie wie Gruppe 3 + Physiotherapie mit VRP1 Desitin, Gruppe 2: Therapie wie Gruppe 3 + Therapie mit dem RC-Cornet®, Gruppe 3: Kontrollgruppe (tgl. 40 mg Prednisolon i.v., 2x tgl. Theophyllin i.v. nach Spiegel und 3x tgl. Inhalation mit ß2 + Parasympathikolytikum im Düsenvernebler). Kontrollen an den Tagen 1, 4 und 7 jeweils vor und nach Physiotherapie. Erfragen von Atemnot, Husten, Auswurf und Akzeptanz der Methoden über Visualanalogskalen. Unter RC-Cornet® sinkt zu Beginn das Residualvolumen statistisch signifikant, auch die Hyperventilation ist statistisch signifikant geringer. Die subjektive Bewertung der Patienten bzgl. Auswurf, |

| | |
|---|---|
| | Befinden und Behandlung (eine Zusammenfassung aus Einfachheit und Umgang mit dem Gerät) sind bei dem RC-Cornet® signifikant besser als bei VRP1 Desitin. Bezüglich der Senkung des Hustens wird das Signifikanzniveau mit p<0,055 gerade verfehlt. Das RC-Cornet®stellt somit für die Langzeittherapie der chronisch obstruktiven Bronchitis mit trachealbronchialer Instabilität ein effektives und vom Patienten akzeptiertes, handliches Physiotherapiegerät dar, das mitgetragen werden kann und jederzeit einsatzbereit ist.<br><br>*In a randomized prospective study in 90 patients with COAD and tracheo-bronchial instability 3 groups were formed. Group 1: Therapy as group 3+ Physiotherapy with VRP1 Desitin, Group 2: Therapy as group 3+ Physiotherapy with RC-Cornet, Group 3: CONTROL GROUP: daily 40 mg prednisolon i.v., 2 x theophylline i.v. in relation to serum levels and 3 x inhalation of beta 2+ parasympathicolytic with a compressor inhaler. Therapy group 1 and 2 received the same drug and inhalation therapy as the controls. Controls of lung function before and after physiotherapy and visual analog scales for dyspnoea, cough, sputum and acceptance of the physiotherapy were performed at days 1, 4 and 7. With RC-Cornet the residual volume decreases statistically significant in comparison to VRP1 Desitin. Hyperventilation is also statistically significant smaller in RC-Cornet compared to VRP1 Desitin. The subjective improvement of sputum, dyspnoea and acceptance of the method of physiotherapy was statistically significant better for RC-Cornet. Regarding cough the significance was just failed by p < 0.055. RC-Cornet is a comfortable, effective, small accepted tool for the long term physiotherapy of patients with COAD and tracheobronchial instability.* |

| **Titel** | **Sputum rheology changes in cystic fibrosis lung disease following two different types of physiotherapy: flutter vs autogenic drainage.** |
|---|---|
| **Autor/Author** | App EM1, Kieselmann R, Reinhardt D, Lindemann H, Dasgupta B, King M, Brand P. |
| **Journal** | Chest. 1998 Jul;114(1):171-7 |

| | |
|---|---|
| **Abstrakt/ Abstract** | OBJECTIVE: The aim of the present study was to investigate the efficacy of two frequently used physiotherapies (PTs) for the removal of bronchial secretions in cystic fibrosis (CF) lung disease: autogenic drainage (AD) and the Flutter (Desitin in Germany). AD is believed to improve mucus clearance from peripheral to central airways due to airway caliber changes in combination with a special breathing technique. The Flutter is an easy-to-use physiotherapy device based on oscillations of a steel ball during expiration through a pipe-type device.<br>MATERIALS AND METHODS: To evaluate the acute and chronic physiotherapy effects of these two techniques, 14 CF patients underwent either twice daily AD or Flutter treatment for 4 consecutive weeks in a randomized crossover design. Prior to each therapy interval, for a 1-week wash-out period, no PT was administered, but patients continued regular medication. At the beginning and end of each 4-week interval, pulmonary function was measured before and after an acute 30-min therapy. At the end of the PT session, sputum was collected, weighed, and deep frozen until analyzed. The viscoelasticity of the sputum was evaluated using a magnetic microrheometer.<br>RESULTS: No significant changes were noted for FVC, FEV1, or sputum volume throughout the study. Sputum viscoelasticity (rigidity index), however, was significantly lower ($p<0.01$) after therapy with the Flutter in comparison with AD, predicting improvements in mucociliary and cough clearability of the secretions. In a companion in vitro experiment, oscillations generated by passing humidified air over CF sputum lining an acrylic tube connected to a Flutter de-ice were found to decrease sputum elasticity, as measured by a filancemeter. These findings suggest that applied oscillations are capable of decreasing mucus viscoelasticity within the airways at frequencies and amplitudes achievable with the Flutter device, and provide direct evidence that PT can reduce the viscoelasticity of sputum. |

| **Titel** | **Short-term efficacy of RC-Cornet in decreasing cohesivness of sputum in bronchectasis patients - poster presentations** |
|---|---|
| **Autor/Author** | King M, Feng W, Deng WW, Huang SG; Cheng QJ, Cegla UH |
| **Journal** | Chest 1998; 225-230 |
| **Abstrakt/ Abstract** | Objective: the objective of study is to compare between the effectiveness of Quake versus RC-cornet on mucous clearance and to determine patient preference between the two devices.<br>Material and Method: A randomised cross over trial was conducted. The mean age of 35 cases were 52.29± 13.9 Diagnosed to have bronchiectasis, were included in the study by block randomization with inclusion criteria of Sputum volume more than 20ml per 24hours.<br>Results: Quake was more effective in airway clearance as compared to RC-cornet with no carry over effect pvalue of 0.475. Sputum collected after Quake was greater than RC-cornet with |

| | |
|---|---|
| | mean difference of 2.78ml. Patient preference is RC cornet. Conclusion: Quake has a high pulsatile pressure and strong pressure pulses with a raspberry sound produced with oscillation during both phases of respiration, promoting more mucous production, On the contrary RC -Cornet produces high frequency oscillations at low flow with PEP generated by valve sequence. Though Quake has a higher sputum production than Rc cornet but the patient preference is predominant towards RC-cornet.Key words: chest physiotherapy, Quake, RC-cornet, bronchiectasis, oscillation ,positive expiratory pressure, secretion clearance. |

| **Titel** | **Short-term efficacy of RC-Cornet in improving pulmonary function and decreasing cohesiveness of sputum in bronchiectasis patients** |
|---|---|
| **Autor/Author** | W. Feng, MD, W.W. Deng, MD, S.G. Huang MD, Q.J. Cheng, MD, U.H. Cegla. MD, M. King, PhD, FCCp, Pulmonary Research Group, University of Alberta, Edmonton, Canada, Rui Jin Hospital, affiliated to Shanghai Second Medical University, Shanghai, P.R.China; R. Cegla GmbH, Montabaur, Germany |
| **Journal** | Chest 1998; 320S |
| **Abstrakt/ Abstract** | Purpose: The RC-cornet is a recently developed, gravity independent device which produces expiratory airflow oscillations aimed at improving mucus clearance. We wished to evaluate the short term efficacy of Comet therapy in bronchiectasis patients. Methods: Comet oscillations were produced by expiratory flow through the Cornet set in position 4.0. Ten bronchiectasis patients diagnosed by bronchography and CT were randomly selected from outpatients. Pulmonary function (FVC, FEV1, FEV1/FVC), and some clinical symptoms (such as dyspnea) were studied, and sputa were expectorated spontaneously before and after 15 min of Cornet physiotherapy. Spinnability (cohesiveness) and viscoelasticity (G* at 1 and 100 rad/s) of each sputum were analyzed by filancemeter and magnetic rheometer. Results: After 15 min treatment, five patients felt improvement in their dyspnea, while five patients felt no change. There was a significant change of pulmonary function; the FVC increased in all but one patient, and the mean increase of 90 mL was significant (p=.026). There was no change in FEV1 or FEV1/FVC ratio. For sputum rheological properties, the cohesiveness of bronchiectasis sputum (p=.013) and the viscoelasticity (logG*1) (p=.024) both decreased significantly. There was no relationship between the change in pulmonary function and the sputum rheological properties. Conclusions: This short term treatment study in bronchiectasis patients demonstrates that RC-cornet therapy decreases the viscoelasticity and cohesiveness of bronchiectasis sputum and improves pulmonary function. Clinical Implications: Since the Cornet device is inexpensive, portable, and can be used conveniently by patients in any position, we suggest that further long-term clinical studies should be carried out.<br>Short-term efficacy of RC-Cornet in improving pulmonary function |

| | |
|---|---|
| | and decreasing cohesiveness of sputum in bronchiectasis patients. |

| **Titel** | **Comparative evaluation of the Flutter and the Cornet in improving the cohesivness of cystic fibrosis sputum** |
|---|---|
| **Autor/Author** | Dasgupta B., Nakamura S., App EM, King M |
| **Journal** | 11. Annual north american cystic fibrosis conference Nashvill, Tennesse, 23-26 October, proceedings. Pedatr pulmonol suppl 1997; 14: A341 |
| **Abstrakt/ Abstract** | Comprenhensive treatemt pf cystic fibrosis (CF) lung disease consits of measures directed at increasing the clearance of excess bronchial secretions, thus improving lung funktion and oxygenation. The effectivity of the Flutter in improving the viscoelasticity of CF airway secretions has already been established in vivo (Am J Respir Crit Care Med 1995;151:A737). The Cornet, a device similar to the Flutter, assists CF patients in mucus clearance. Our goal was to evaluate the eficacy of the two different devices, the Cornet and the Flutter, on the cohesiveness (thread formation) of CF sputum. Equal volumes of ten different aliquots from pooled CF sputum were subjected to the following protocolls: (…) A reduction of in cohesivness is related to a lower viscoelasticity, thus predicting enhanced clearance of mucus from theairways of CF patients. Although both devices improved the quality of the sputum, this in vitro study suggests that the Flutter is more efficacious then the Cornet in reducing the cohesiveness of CF sputum. This difference between the devices may be a function of the frequency and amplitude of oscillations they generate. (…) |

| **Titel** | **Effects of oscillating air flow on the rheological properties and clearability of mucous gel simulants.** |
|---|---|
| **Autor/Author** | Tomkiewicz RP1, Biviji A, King M. |
| **Journal** | Biorheology. 1994 Sep-Oct;31(5):511-20. |
| **Abstrakt/ Abstract** | This in vitro study addressed the question of clearance-related changes in the physical properties of mucous gel simulants (MGS) subjected to oscillating air flow. Delineating some of the possible mechanisms of action for the reported beneficial effects of high-frequency chest compression (HFCC) therapy constituted the rationale. The rheological variables measured were spinnability by filancemeter and viscoelasticity (mechanical impedance, G*, and loss tangent, tan delta) by magnetic microrheometry. Two derivative parameters, mucociliary clearability index (MCI) and cough clearability index (CCI), were computed from the rheological variables, based on relationships established from model studies of clearance. Two ranges of air flow oscillation frequencies used previously in animal and clinical studies, i.e., 12-13 Hz or 22-23 Hz, were applied. The measurements were made after application of oscillating air flow for 15, 30 and 60 minutes, and compared with those at baseline and negative control. A |

| | |
|---|---|
| | significant decrease in log G* with administration of oscillations was observed (p = 0.06 at 30 minutes, p < 0.01 at 60 minutes, for G* measured at 1 rad/s). Spinnability also decreased by 19.3% and 30.7% after 15 minutes; 32.9% and 41.1% after 30 minutes; 36.4% and 50.5% after 60 minutes, for 12 Hz and 22 Hz, respectively (all significantly different from baseline). There was a positive correlation between viscoelasticity and spinnability, and a negative correlation between spinnability and CCI, but no correlation between spinnability and MCI. Oscillating air flow seemed to act as a physical "mucolytic" that affected mostly the cough clearability of the mucus simulant. |

| **Titel** | **Efficacy of the Flutter device for airway mucus clearance in patients with cystic fibrosis.** |
|---|---|
| **Autor/Author** | Konstan MW1, Stern RC, Doershuk CF. |
| **Journal** | J Pediatr. 1994 May;124(5 Pt 1):689-93. |
| **Abstrakt/ Abstract** | The Flutter is a handheld device designed to facilitate clearance of mucus in hypersecretory lung disorders. Exhalation through the Flutter results in oscillations of expiratory pressure and airflow, which vibrate the airway walls (loosening mucus), decrease the collapsibility of the airways, and accelerate airflow, facilitating movement of mucus up the airways. We studied 18 patients with cystic fibrosis and mild to moderate lung disease to determine the efficacy of the Flutter in clearing mucus from the airways. The amount of sputum expectorated (measured by weight) when the Flutter was used was compared with the amount expectorated with vigorous voluntary coughing and with postural drainage (chest percussion and vibration). The amount of sputum expectorated by subjects using the Flutter was more than three times the amount expectorated with either voluntary cough or postural drainage (p < 0.001). There were no adverse effects. The Flutter is simple to use, inexpensive, and fully portable, and once the patient and family are instructed in its use, it does not require the assistance of a caregiver. For hospitalized patients, elimination of the need for a therapist could reduce health care costs. Long-term studies of the use of the Flutter seem justified to determine its effects on pulmonary function and outcome. |

| **Titel** | **Removal of excessive bronchial secretions by asymmetric high-frequency oscillations** |
|---|---|
| **Autor/Author** | L. Freitag, W. M. Long, C. S. Kim,A. Wanner |
| **Journal** | 01 Aug 1989https://doi.org/10.1152/jappl.1989.67.2.614 |
| **Abstrakt/ Abstract** | The present study evaluated whether high-frequency oscillations (HFO) with biased flow profiles applied at the airway opening are capable of altering mucus clearance. In eight anesthetized sheep, artificial mucus (100 P) was infused continuously (1 ml/min) into the left main bronchus via a cannula inserted through the dorsal |

| | |
|---|---|
| | wall of the left main bronchus after thoracotomy. Outcoming mucus was collected every 10 min from the end of a cuffed orotracheal tube. Animals were ventilated with a Harvard respirator at a low frequency with superimposed HFO at 14 Hz with asymmetrical waveforms generated by a digitally controlled electromagnetic piston pump (expiratory bias: peak expiratory flow 3.8 l/s, peak inspiratory flow 1.3 l/s; inspiratory bias: reverse of expiratory bias). The influence of posture and of HFO airflow bias on mucus clearance was determined. In the horizontal position, mucus clearance with expiratory biased HFO was 3.5 +/- 2 (SD) ml/10 min. Head-down tilt produced a clearance of 3.1 +/- 3 ml/10 min; addition of HFO with expiratory bias increased clearance to 11.0 +/- 2.0 ml/10 min (P less than 0.05). No clearance occurred with inspiratory biased HFO during head-down tilt. These results indicate that expiratory biased HFO at the airway opening can clear excessive airway secretions and augment clearance by postural drainage. |

## 3. Leitlinien und deren Updates / *Guidelines and Updates*

| **Titel** | **British Thoracic Society Guideline for Non-CF Bronchiectasis - A Quick Reference Guide** |
|---|---|
| **Autor/Author** | Pasteur MC, Bilton D, Hill AT; British Thoracic Society Bronchiectasis non-CF Guideline Group |
| **Journal** | Thorax. 2010 Jul;65 Suppl 1:i1-58. doi: 10.1136/thx.2010.136119 |
| **Abstrakt/ Abstract** | The diagnosis, investigation and particularly management of bronchiectasis has been largely empirical and the subject of relatively few controlled clinical trials. There are no clear guidelines, although an Australian position statement has been published concerning bronchiectasis in children. The purposes of these guidelines were therefore threefold: (1) to identify relevant studies in noncystic fibrosis (CF) bronchiectasis; (2) to provide guidelines on management based on published studies where possible or a consensus view; and (3) to identify gaps in our knowledge and identify areas for future study. |

| **Titel** | **Leitlinie zur Diagnostik und Therapie von Patienten mit chronisch obstruktiver Bronchitis und Lungenemphysem (COPD) herausgegeben von der Deutschen Gesellschaft für Pneumologie und Beatmungsmedizin e.V. und der Deutschen Atemwegsliga e.V., unter Beteiligung der Österreichischen Gesellschaft für Pneumologie**<br><br>***Guideline for the Diagnosis and Treatment of COPD Patients*** |
|---|---|

| | |
|---|---|
| | ***Issued by the German Respiratory Society and the German Atemwegsliga in Cooperation with the Austrian Society of Pneumology (only in German language available)*** |
| **Autor/Author** | C. Vogelmeier, R.Buhl, O. Burghuber, C.-P.Criée, S.Ewig, J. Godnic-Cvar, S.Hartl, F.Herth, P.Kardos, K. Kenn, D.Nowak, K.F.Rabe, M.Studnicka, H.Watz, T.Welte, W. Windisch, H.Worth |
| **Journal** | DOI https://doi.org/10.1055/s-0043-125031 Online-Publikation: 9.3.2018 \| Pneumologie 2018; 72: 253 – 308 © Georg Thieme Verlag KG Stuttgart · New York ISSN 0934-838 |
| **Abstrakt/ Abstract** | Das vorliegende Dokument ist eine Neufassung und Aktualisierung der Leitlinie zur Diagnostik und Therapie von Patienten mit COPD, die die bisherige Version aus dem Jahr 2007 ablöst. Die Fülle an neuen Erkenntnissen zu Risikofaktoren, Diagnostik, Schweregradeinschätzung, Prävention und medikamentösen sowie nicht medikamentösen Therapiemaßnahmen machten eine umfassende Überarbeitung erforderlich. Die neue Leitlinie baut auf das GOLD-Dokument unter Berücksichtigung von Besonderheiten in Deutschland und Österreich auf.<br><br>*This document is a revision of the guideline for diagnosis and treatment of COPD that replaces the version from 2007. A multitude of recent reports regarding risk factors, diagnosis, assessment, prevention and pharmacological as well as non pharmacological treatment options made a major revision mandatory. The new guideline is based on the GOLD document taking into account specifics in Germany and Austria.* |

| **Titel** | **Guidelines for the Physiotherapy Management of the Adult, Medical, Spontaneously Breathing Patient<br>British Thoracic Society Physiotherapy Guideline Development Group** |
|---|---|
| **Autor/Author** | Bott J, Blumenthal S, Buxton M, Ellum S, Falconer C, Garrod R, Harvey A, Hughes T, Lincoln M, Mikelsons C, Potter C, Pryor J, Rimington L, Sinfield F, Thompson C, Vaughn P, White J; British Thoracic Society Physiotherapy Guideline Development Group |
| **Journal** | Thorax. 2009 May;64 Suppl 1:i1-51. doi: 10.1136/thx.2008.110726 |
| **Abstrakt/ Abstract** | Physiotherapy should be offered to patients with a variety of medical respiratory conditions, with the aim of breathlessness management and symptom control, mobility and function improvement or maintenance, and airway clearance and cough enhancement or support. Strategies and techniques include: rehabilitation, exercise testing (including for ambulatory oxygen assessment), exercise prescription, airway clearance, and positioning and breathing techniques. Physiotherapy may be helpful for postural and/or musculoskeletal dysfunction and pain, and provide help in improving continence, especially during coughing and forced expiratory manoeuvres. Physiotherapists are usually central to the delivery of pulmonary rehabilitation and may be instrumental in the non-invasive ventilation service. |

| | |
|---|---|
| | Physiotherapists are frequently involved in the delivery of oxygen and some nebulised substances, as well as providing vital monitoring of, for example, ventilatory function and cough effectiveness. Some complementary therapies may be appropriate in some situations (Web Appendix 1). |

| **Titel** | **Leitlinie zur Diagnostik und Therapie von Patienten mit Asthma**<br><br>***Guidelines for Diagnosis and Treatment of Asthma Patients (only in German language available)*** |
|---|---|
| **Autor/Author** | R.Buhl, D.Berdel, C.-P.Criée, A.Gillissen, P.Kardos, C.Kroegel, W.Leupold, H.Lindemann, H.Magnussen, D.Nowak, D.Pfeiffer-Kascha, K.Rabe, M.Rolke, G.Schultze-Werninghaus, H.Sitter, D.Ukena, C.Vogelmeier, T.Welte, R.Wettengel, H.Worth |
| **Journal** | Pneumologie 2006; 60; Seite 139-183; Georg Thieme Verlag KG Stuttgart´ N |
| **Abstrakt/ Abstract** | Atem- und Physiotherapieformen können in Einzelfällen sinnvoll sein [246,247] und werden im Rahmen von Rehabilitationsprogrammen regelhaft angewandt. Die Atemphysiotherapie stellt eine flankierende Maßnahme dar. Neben der medikamentösen Therapie hat sie das Ziel, den Patienten im Selbstmanagement der Erkrankung zu unterstützen, dyspnoebedingte Angst und Atemnot zu lindern und damit die Lebensqualität zu erhöhen. Mittels physiotherapeutischer Techniken erlernen die Patienten, den in- und exspiratorischen Atemfluss zu verlangsamen, den Pharynx zu erweitern wie auch die Atemwege bei forcierter Exspiration offenzuhalten. Ziel ist die Reduktion erhöhter Atemarbeit. (...) Bei ausgeprägter Dyskrinie unterstützen Atemtechniken mit deutli-<br>chen atemsynchronen Bronchialkaliberschwankungen und PEP-Atmung mit• Oszillationen die Sekretmobilisation und den Sekrettransport. |

| **Titel** | **Clinical Guidelines for the Physiotherapy management of cystic fibrosis** |
|---|---|
| **Autor/Author** | Recommendations of a Working Group, Jan. 2002 |
| **Journal** | Cystic Fibrosis Trust 2002, ISBN 0- 9540536-4-8, Page 11-16 |
| **Abstrakt/ Abstract** | (...) Oscillating positive expiratory pressure - RC-Cornet® (Cornet) The RC-Cornet® is a curved tube that contains within its plastic casing a flexible inner tube. During expiration through the device, there is a slight positive expiratory pressure and an oscillation of the air within the airways. The pressure and flow can be varied, by rotating the mouthpiece, until an optimal effect is felt to facilitate airway clearance. (...) Positive expiratory pressure therapy increases intrabronchial pressure in central and peripheral airways splinting the airways open and preventing compression induced by airway collapse. This promotes inflow of air behind mucus |

| | |
|---|---|
| | obstructions either via a bronchial route or collateral airway channels. Smaller bronchial airways are prevented from collapse thus permitting the continuing upward movement of secretions. Several studies to date report PEP to be an acceptable and effective treatment regimen. (...) High pressure PEP is a modification of the original PEP technique. As disease severity increases, hyperinflation (due to obstructive secretions) and airway instability (due to airway damage) become increasing problems. Trapping of secretions distal to areas of airway collapse during forced expiration may have a negative effect on clearance. By performing forced expiration against a fixedresistance this effect may be negated. (...) |

| **Titel** | **Clinical Guidelines for the Physiotherapy management of cystic fibrosis** |
|---|---|
| **Autor/Author** | Recommendations of a Working Group, Jan. 2002 |
| **Journal** | Cystic Fibrosis Trust 2002, ISBN 0- 9540536-4-8, Page 11-16 |
| **Abstrakt/ Abstract** | (...) Oscillating positive expiratory pressure - RC-Cornet® (Cornet) The RC-Cornet® is a curved tube that contains within its plastic casing a flexible inner tube. During expiration through the device, there is a slight positive expiratory pressure and an oscillation of the air within the airways. The pressure and flow can be varied, by rotating the mouthpiece, until an optimal effect is felt to facilitate airway clearance. (...) Positive expiratory pressure therapy increases intrabronchial pressure in central and peripheral airways splinting the airways open and preventing compression induced by airway collapse. This promotes inflow of air behind mucus obstructions either via a bronchial route or collateral airway channels. Smaller bronchial airways are prevented from collapse thus permitting the continuing upward movement of secretions. Several studies to date report PEP to be an acceptable and effective treatment regimen. (...) High pressure PEP is a modification of the original PEP technique. As disease severity increases, hyperinflation (due to obstructive secretions) and airway instability (due to airway damage) become increasing problems. Trapping of secretions distal to areas of airway collapse during forced expiration may have a negative effect on clearance. By performing forced expiration against a fixedresistance this effect may be negated. (...) |

# 4. RC-Cornet® N / RC-Cornet® PLUS NASAL

| **Titel** | **United airway disease: current perspectives** |
|---|---|
| **Autor/Author** | Giavina-Bianchi P, Aun MV, Takejima P, Kalil J, Agondi RC. |
| **Journal** | J Asthma Allergy. 2016 May 11;9:93-100. doi: 10.2147/JAA.S81541. eCollection 2016 |
| **Abstrakt/ Abstract** | Upper and lower airways are considered a unified morphological and functional unit, and the connection existing between them has been observed for many years, both in health and in disease. There is strong epidemiologic, pathophysiologic, and clinical |

| | |
|---|---|
| | evidence supporting an integrated view of rhinitis and asthma: united airway disease in the present review. The term "united airway disease" is opportune, because rhinitis and asthma are chronic inflammatory diseases of the upper and lower airways, which can be induced by allergic or nonallergic reproducible mechanisms, and present several phenotypes. Management of rhinitis and asthma must be jointly carried out, leading to better control of both diseases, and the lessons of the Allergic Rhinitis and Its Impact on Asthma initiative cannot be forgotten. |

| **Titel** | **Drug Delivery to Paranasal Sinuses - Deposition Pattern and Clearance in Healthy Volunteers** |
|---|---|
| **Autor/Author** | Möller W, Schuschnig U, Bartenstein P, Meyer G, Häussinger K, Schmid O, Becker S |
| **Journal** | J Aerosol Med Pulm Drug Deliv. 2014 Aug;27(4):255-63. doi: 10.1089/jamp.2013.1071 |
| **Abstrakt/ Abstract** | Chronic rhinosinusitis (CRS) is the major disorder of the upper airways, affecting about 10-15% of the total population. Topical treatment regimens show only modest efficacy, because drug delivery to the posterior nose and paranasal sinuses is still a challenge. Therefore, there is a high rate of functional endoscopic sinus surgery in CRS patients. Most nasally administered aerosolized drugs, like nasal pump sprays, are efficiently filtered by the nasal valve and do not reach the posterior nasal cavity and the sinuses, which are poorly ventilated. However, as highlighted in this review, sinus ventilation and paranasal aerosol delivery can be achieved by using pulsating airflow, offering new topical treatment options for nasal disorders. Radioaerosol inhalation and imaging studies in nasal casts and in healthy volunteers have shown 4-6% of the nasally administered dose within the sinuses. In CRS patients, significant aerosol deposition in the sinus cavities was reported before sinus surgery. After surgery, deposition increased to the amount observed in healthy volunteers. In addition, compared with nasal pump sprays, retention kinetics of the radiolabel deposited in the nasal cavity was prolonged, both in healthy volunteers and in CRS patients. These efficiencies may be sufficient for topical aerosol therapies of sinus disorders and, due to the prolonged retention kinetics, may reduce application modes, but have to be proven in future clinical trials. Pulsating aerosols may offer additional new topical treatment options of nasal and sinus disorders before as well as after surgery. |

| **Titel** | **Management of the upper airway in cystic fibrosis** |
|---|---|
| **Autor/Author** | Illing EA1, Woodworth BA |
| **Journal** | Curr Opin Pulm Med. 2014 Nov;20(6):623-31. doi: 10.1097/MCP.0000000000000107 |
| **Abstrakt/ Abstract** | PURPOSE OF REVIEW: Upper airway disease engenders significant morbidity for patients with cystic fibrosis and is increasingly recognized as having a much greater role in |

| | |
|---|---|
| | pulmonary outcomes and quality of life than originally believed. Widespread disparate therapeutic strategies for cystic fibrosis chronic rhinosinusitis underscore the absence of a standardized treatment paradigm. This review outlines the most recent evidence-based trends in the management of upper airway disease in cystic fibrosis. RECENT FINDINGS:<br>The unified airway theory proposes that the sinuses are a focus of initial bacterial colonization which seeds the lower airway and may play a large role in maintaining lung infections. Mounting evidence suggests more aggressive treatment of the sinuses may confer significant improvement in pulmonary disease and quality of life outcomes in cystic fibrosis patients. However, there is a lack of high-level evidence regarding medical and surgical management of cystic fibrosis chronic rhinosinusitis that makes generalizations difficult.<br>SUMMARY: Well designed clinical trials with long-term follow-up concerning medical and surgical interventions for cystic fibrosis sinus disease are required to establish standardized treatment protocols, but increased interest in the sinuses as a bacterial reservoir for pulmonary infections has generated considerable attention. |

| **Titel** | **Pulsating airflow and drug delivery to paranasal sinuses** |
|---|---|
| **Autor/Author** | Möller W, Lübbers C, Münzing W, Canis M. |
| **Journal** | Curr Opin Otolaryngol Head Neck Surg. 2011 Feb;19(1):48-53. doi: 10.1097/MOO.0b013e3283420f39. |
| **Abstrakt/ Abstract** | PURPOSE OF REVIEW: There is a high incidence of nasal disorders, including chronic rhinosinusitis (CRS), affecting about 14% of the total population. Topical treatment regimens show only limited efficacy of drug delivery to the posterior nose and paranasal sinuses. Nevertheless, the primary treatment option of CRS is a combination of topical or systemic steroids, antibiotics and functional endonasal sinus surgery (FESS). RECENT FINDINGS: Sinus ventilation and paranasal aerosol deposition can be achieved by using pulsating airflow. Studies using pulsating airflow in nasal casts and in healthy volunteers have shown that up to 8% of the nasally deposited drug can deposit within the sinuses, which could not be achieved using nasal pump sprays. In addition, compared with nasal pump sprays, retention kinetics of the radiolabel deposit in the nose was prolonged. SUMMARY: With this efficiency, topical aerosol therapies of sinus disorders can be achieved and, due to the prolonged retention, reduced application modes are possible. This offers new treatment options of sinus-nasal disorders prior or after FESS. |

| **Titel** | **Effects of nasal positive expiratory pressure on dynamic hyperinflation and 6-Minute walk test in patients with COPD** |
|---|---|
| **Autor/Author** | Wibmer T, Rüdiger S, Heitner C, Kropf-Sanchen C, Blanta I, Stoiber KM, Rottbauer W, Schumann C. |

| | |
|---|---|
| **Journal** | Respir Care. 2014 May;59(5):699-708. doi: 10.4187/respcare.02668. Epub 2013 Oct 29 |
| **Abstrakt/ Abstract** | BACKGROUND: Although there is a high incidence of nasal disorders including chronic sinusitis, there is limited success in the topical drug delivery to the nose and the paranasal sinuses. This is caused by the nose being an efficient filter for inhaled aerosol particles and the paranasal sinuses being virtually non-ventilated. METHOD: The objective of this study was to visualize the efficiency of sinus ventilation in healthy volunteers using dynamic 81mKr-gas imaging in combination with pulsating airflows. Furthermore, the deposition and retention of 99mTc-DTPA aerosol particles was assessed. RESULTS: The ventilation of the maxillary and frontal sinuses could be visualized by gamma camera imaging during pulsating airflow. In addition, using pulsating airflow, between 3% and 5% of nasally deposited aerosols penetrated into the paranasal sinuses while during application without pulsation aerosol deposition was below 1%. Furthermore pulsation increased aerosol deposition in the nasal airways by a factor of three. CONCLUSIONS: The study demonstrates the high efficiency of a pulsating airflow in paranasal sinus ventilation and aerosolized drug delivery. This proves that topical drug delivery to the paranasal sinuses in relevant quantities is possible and indicates further clinical studies are necessary. |

| **Titel** | **Does nasal irrigation enter paranasal sinus in chronic rhinosinusitis?** |
|---|---|
| **Autor/Author** | Snidvongs K, Chaowanapanja P, Aeumjaturapat S, Chusakul S, Praweswararat P |
| **Journal** | American Journal Rhinology 2008 Sep-Oct;22(5):483-6. doi: 10.2500/ajr.2008.22.3221 |
| **Abstrakt/ Abstract** | BACKGROUND: Nasal irrigation is widely used in treating sinonasal diseases. Not only does it remove static secretions and promote mucociliary clearance, but, in chronic rhinosinusitis, nasal flush is also a potential route for topical drug administration into paranasal sinuses. A clinical study was conducted to investigate how well nasal irrigation could reach paranasal sinuses with the ostiomeatal units blocked in chronic rhinosinusitis. This study was performed to (1) assess the ability of a nasal douche and spray to deliver a solution into the paranasal sinuses in chronic rhinosinusitis and (2) compare the performance of the two techniques. METHODS: Fourteen patients, with bilateral chronic rhinosinusitis, underwent nasal irrigation with 140 mg/mL of iodinated contrast solution by 40 mL of douching using an irrigation syringe in one side, and 10 mL of spraying in the other side. A computed tomography scan was undertaken for each patient to determine the volume and the distribution of staining in the nose and paranasal sinuses. RESULTS: Only two patients had any staining, with a small amount present in a total of three maxillary sinuses (0.10 mL, 0.04 mL, and 0.13 mL). The mean |

| | |
|---|---|
| | volumes of paranasal sinus staining by nasal douche and nasal spray were 0.0093 and 0.01 mL, respectively. We found that the two techniques had a similar performance. Both of them delivered only a small amount of the solution, if any, into the sinuses (with a mean difference of -0.0007 mL; 95% CI, -0.02-0.02 mL; p = 0.94). CONCLUSION: Nasal douche and spray is not effective in delivering a nasal irrigation solution into paranasal sinuses in chronic rhinosinusitis. |

| **Titel** | **Ventilation and drug delivery to the paranasal sinuses: studies in a nasal cast using pulsating airflow** |
|---|---|
| **Autor/Author** | Möller W, Schuschnig U, Meyer G, Mentzel H, Keller M |
| **Journal** | Rhinology. 2008 Sep;46(3):213-20 |
| **Abstrakt/ Abstract** | BACKGROUND: Although there is a high incidence of nasal disorders including chronic sinusitis, there is limited success in the topical drug delivery to the nose and the paranasal sinuses. This is caused by the nose being an efficient filter for inhaled aerosol particles and the paranasal sinuses being virtually non ventilated. METHOD: The objective of this study was to visualize the efficiency of sinus ventilation in a nasal cast using dynamic 81mKr-gas imaging in combination with pulsating airflows. Furthermore, the efficiency of the deposition of radiolabelled aerosol was assessed. RESULTS: Pulsation increased ventilation efficiency of the sinuses more than fivefold and aerosol deposition efficiency more than twentyfold, compared to delivery without pulsation. Furthermore pulsation increased aerosol deposition in the nasal airways by a factor of three. Using pulsating airflow Kr-gas ventilation and aerosol deposition efficiencies increased with increasing sinus volume. Pulsating airflow resulted in a deposition of up to 8% of the nebulized drug within the sinuses compared to 0.2% without pulsation. CONCLUSIONS: The study demonstrates the high efficiency of a pulsating airflow in paranasal sinus ventilation and aerosolized drug delivery. This proves that topical drug delivery to the paranasal sinuses in relevant quantities is possible. |

| **Titel** | **Physiotherapie der chronischen Rhino-Sinusitis (Postnasal drip Syndrom) mit dem RC-Cornet® N (only in German language available)** |
|---|---|
| **Autor/Author** | U.H. Cegla; A.Harten |
| **Journal** | Luft, Sonderdruck aus Band 3, Heft 1, 15. Januar 1998 |
| **Abstrakt/ Abstract** | Eine Sinusitis (Nasennebenhöhlenentzündung) gilt dann als chronisch, wenn sie mehr als zwei bis drei Monate andauert. Die Patienten leiden unter ständig eitrigem Nasensekret mit verstopfter Nase und Husten, eventuell unter Kopfschmerzen und allgemein unter einer Beeinträchtigung des Wohlbefindens. Eine wirkungsvolle Therapie sorgt dafür, dass der hartnäckige Schleim in den Nasennebenhöhlen verflüssigt wird und damit leichter |

| | |
|---|---|
| | abfließen kann. Das RC-Cornet®N ist das atemtherapeutische Hilfs- mittel zum Lösen von Sekreten im Nasen-Rachen-Raum und zur Behandlung von Belüftungsstörungen der Nasennebenhöhlen. |

| **Titel** | **Ventilation and aerosolized drug delivery to the paranasal sinuses using pulsating airflow - A preliminary study** |
|---|---|
| **Autor/Author** | Moeller W, Schuschnig U, Meyer G, Häussinger K, Keller M, Junge-Hülsing B, Mentzel H |
| **Journal** | Rhinology. 2009 Dec;47(4):405-12. doi: 10.4193/Rhin08.180 |
| **Abstrakt/ Abstract** | BACKGROUND: Although there is a high incidence of nasal disorders including chronic sinusitis, there is limited success in the topical drug delivery to the nose and the paranasal sinuses. This is caused by the nose being an efficient filter for inhaled aerosol particles and the paranasal sinuses being virtually non-ventilated. METHOD: The objective of this study was to visualize the efficiency of sinus ventilation in healthy volunteers using dynamic 81mKr-gas imaging in combination with pulsating airflows. Furthermore, the deposition and retention of 99mTc-DTPA aerosol particles was assessed. RESULTS: The ventilation of the maxillary and frontal sinuses could be visualized by gamma camera imaging during pulsating airflow. In addition, using pulsating airflow, between 3% and 5% of nasally deposited aerosols penetrated into the paranasal sinuses while during application without pulsation aerosol deposition was below 1%. Furthermore pulsation increased aerosol deposition in the nasal airways by a factor of three. CONCLUSIONS: The study demonstrates the high efficiency of a pulsating airflow in paranasal sinus ventilation and aerosolized drug delivery. This proves that topical drug delivery to the paranasal sinuses in relevant quantities is possible and indicates further clinical studies are necessary. |

| **Titel** | **Die Ballondilatation der Eustachischen Röhre zur Behandlung der obstruktiven Tubendysfunktion (only in German language available)** |
|---|---|
| **Autor/Author** | T. Ockermann |
| **Journal** | Dissertation, Hohen Medizinischen Fakultät der Ruhr-Universität Bochum; 2010 |
| **Abstrakt/ Abstract** | Die Funktionsstörung der Eustachischen Röhre, insbesondere die obstruktive Tubendysfunktion, führen zu inadäquatem Druckausgleich des Mittelohres und des pneumatisiertem Mastoids. Dies kann zu einer Reihe von Beschwerden wie Druck- und Völlegefühl im Bereich des Ohres aber auch zu Folgeerkrankungen, die bei Fortbestehen zu einer Destruktion des Warzenfortsatzes und des audiosensiblen Organs führen. Nach heutigem Wissensstand sind ein großer Teil der chronisch |

| | |
|---|---|
| | entzündlichen Mittelohrerkrankungen, mit oder ohne Entwicklung eines Cholesteatoms, auf eine Minderbelüftung der Pauke zurückzuführen.<br>Die Behandlung der obstruktiven Tubendysfunktion, insbesondere die chirurgische, stellt bis heute eine große Herausforderung dar und hat in der prophylaktischen Therapie von chronischen Mittelohrerkrankungen einen hohen Stellenwert. Mit den derzeitigen Behandlungsmethoden wie z.B. der wiederholten Einlage von Paukenröhrchen, die tympanale Tuben-katheterisierung mit Golddrähten, aufwendigen transmastoidale Shuntoperationen oder auch die Lasertuboplastie konnten bisher keine adäquaten klinischen Ergebnisse erzielt werden. Ein Teil dieser Methoden befinden sich noch in der klinischen Erprobung. Ein allgemein gültiges und standardisiertes Behandlungsverfahren liegt derzeit noch nicht vor. |

| **Titel** | **Novel drug-delivery systems for patients with chronic rhinosinusitis** |
|---|---|
| **Autor/Author** | Silviu Albu |
| **Journal** | Drug Design, Development and Therapy 2012:6 125-132 |
| **Abstrakt/ Abstract** | Chronic rhinosinusitis, one of the most common chronic medical complaints in the United States, seems to be increasing in incidence and prevalence, and has a significant impact on quality of life. Topical forms of medical therapy represent an attractive alternative for drug delivery to the nasal cavity and paranasal sinuses. Topical drug delivery has the advantage of directly acting on the site of inflammation, producing a higher concentration at the target site while avoiding systemic side effects. Although considerable research has been undertaken into improving nasal formulations in order to enhance absorption, little attention has so far been directed to upgrading the delivery devices. The aim of this review is to present current knowledge on the novel drug-delivery devices in use in the management of chronic rhinosinusitis patients, and to present the current available knowledge on topical drug penetration into the sinuses using various delivery devices. Additionally, methods used to enhance fluid sinus deposition are presented and the published clinical studies on the results of nebulized antibiotics in the treatment of chronic rhinosinusitis patients are discussed. |

| **Titel** | **Radiographic Comparison of Three Methods for Nasal Saline Irrigation** |
|---|---|
| **Autor/Author** | Olson DE, Rasgon BM, Hilsinger RL Jr. |
| **Journal** | Laryngoscope. 2002 Aug;112(8 Pt 1):1394-8. |
| **Abstrakt/ Abstract** | OBJECTIVE: To compare intranasal distribution of saline solution delivered by three popular methods for<br>nasal saline irrigation. STUDY DESIGN: Prospective, controlled comparison. METHODS: Eight healthy adult volunteers received nasal irrigation with 40 mL of isotonic, nonionic contrast material |

| | |
|---|---|
| | immediately before having coronal computed tomography to visualize distribution of solution in the paranasal sinuses. For each study subject, three methods of irrigation were used: irrigation using positive-pressure irrigation, irrigation using negative-pressure irrigation, and irrigation using a nebulizer. For each subject, three-dimensional computer reconstructions of the irrigated paranasal sinus airspaces were used to compare contrast solution volume and distribution achieved by the three methods. RESULTS: Of the three methods used, two methods, positive-pressure and negative-pressure irrigation, distributed contrast solution widely to ethmoid and maxillary sinuses, but distribution of contrast solution was more uniform using positive-pressure irrigation than using negative-pressure irrigation. The nebulization method distributed contrast solution poorly and resulted in a significantly lower volume of retained contrast solution (P <.05). CONCLUSION: Judged solely on the basis of solution distribution in the nasal sinuses, nasal irrigation is effective when either positive-pressure or negative-pressure irrigation is used but is ineffective when a nebulizer is used. |

| **Titel** | **Leitlinie der Deutschen Gesellschaft für Pneumologie und Beatmungsmedizin zur Diagnositk und Therapie von erwachsenen Patienten mit aktuem chronischem Husten (only in German language available)** |
|---|---|
| **Autor/Author** | P.Kardos; H.Beck; K.-H. Fuchs; A. Gillissen, L. Klimek, H. Morr, D. Pfeiffer-Kascha, G. Schultze-Werninghaus, H.Sitter; T. Voshaar; H.Worth |
| **Journal** | Pneumologie 2010; 64:336-373 |
| **Abstrakt/ Abstract** | Ziele: 'Evidenz'-basierte Empfehlungen für Ärzte zur Verbesserung der Diagnostik und Therapie des Hustens zu geben. Erstellung: Nach elektronischer Literaturrecherche wurde vom federführenden Autor ein erster aktualisierter Entwurf der Leitlinie erstellt und an die von der Leitlinienkomission der Deutschen Gesellschaft für Pneumologie und Beatmungsmedizin benannten Koautoren (Ärzte verschiedener Fachrichtungen, Vertreter der Fachgesellschaften, Patientenvertreter, Physiotherapeutenverband) geschickt. Das Ergebnis der Literaturrecherche mit potentiell relevanten Arbeiten wurde in 4 Teilgebiete aufgeteilt und an jeweils zwei Koautoren zur Begutachtung in Hinblick auf die Einbringung in die Leitlinie geschickt. In zwei Konsensustreffen und in Delphi Verfahren sowie nach Begutachtung durch zwei unabhängige Pneumologen entstand die endgültige Version und eine Kurzversion. Eine weitere Version für Patienten wird erstellt. Ergebnisse: Das Symptom Husten wurde als akut oder chronisch klassifiziert und verschiedenen Krankheitsbildern zugeordnet. Diagnostische Algorithmen für die Abklärung des akuten und des chronischen Hustens wurden zum Teil neu entwickelt, auf die häufigsten Fehler in der Diagnostik und auf Kostengesichtspunkte hingewiesen. Falls eine kausale Therapie nicht möglich oder nicht |

| | |
|---|---|
| | ausreichend ist, sollte die symptomatische Therapie eingeleitet werden. Therapeutische Maßnahmen wurden nach Wirkungsmechanismus aufgeführt. Komplikationen des Hustens und Vorschläge für das Qualitätsmanagement wurden genannt. Evidenz': Empfehlungsgrad und Nachweisstärke der Effektivität wurden entsprechend dem GRADE System (The Grades of Recommendation, Assessment, Development and Evaluation) [10] beurteilt. NUTZEN: Die Leitlinie hilft mit ihrer Systematik auch schwer zu diagnostizierende Patienten mit Husten zielgerichtet, beschleunigt und kostensparend abzuklären. Hierdurch werden die Symptomatik und Lebensqualität der betroffenen Patienten gebessert, wenngleich hierfür keine 'Evidenz' basierten Daten vorliegen. Kosten: Kostengesichtspunkte wurden weitestgehend berücksichtigt. Es konnte 'Evidenz' basiert angegeben werden, ab welchem Zeitpunkt nach Auftreten des Hustens eine intensive Diagnostik erforderlich ist und welche Reihenfolge der Untersuchungen aufgrund der Symptome und der Häufigkeit der Ursache am zweckmäßigsten und kostengünstigsten ist. Wirksamkeit der Empfehlungen: Es ist mit höchstem 'Evidenz'grad belegt, dass die überwältigende Mehrheit der Patienten mit Husten abgeklärt und einer wirksamen Therapie zugeführt werden kann. |

| **Titel** | **Intranasal deposition of nebulized saline: a radionuclide distribution study** |
|---|---|
| **Autor/Author** | Hwang PH, Woo RJ, Fong KJ |
| **Journal** | American Journal Rhinology 2006 May-Jun;20 (3): 255-61 |
| **Abstrakt/ Abstract** | BACKGROUND: Despite the popularity of various nasal sprays and nebulizers, there are limited data regarding the anatomic distribution of particles generated by these devices. This pilot study sought to characterize distribution patterns of nebulized and sprayed saline particles in normal subjects and postsurgical sinus patients.<br>METHODS: Fifteen subjects were studied in three trials: metered-dose nasal spray bottle versus vortex-propelled nebulizer in normal subjects, passive-diffusion nebulizer versus vortex nebulizer in normal subjects, and passive nebulizer versus vortex nebulizer in postsurgical sinus patients. Radiolabeled saline was administered, and nose, lungs, and stomach were imaged. Images were scored by four blinded reviewers for degree of penetration at nine anatomic subsites. RESULTS: Compared with spray bottle, the vortex nebulizer showed more focal intranasal distribution with reduced nasopharyngeal, pharyngeal, and gastric penetration in normal subjects. Three of five subjects showed probable frontal sinus penetration by vortex nebulizer, but no other sinus penetration was noted. No patients showed sinus penetration with the spray bottle. In a separate trial against the passive nebulizer, the vortex nebulizer again showed a greater tendency for sinus penetration in normal subjects, with three of five showing some degree of sphenoid penetration and one of five |

| | |
|---|---|
| | showing slight maxillary penetration. In contrast, no sinus penetration was observed with the passive nebulizer. In the postsurgical patient cohort, minimal sinus penetration was noted with either the vortex nebulizer or the passive nebulizer. Despite surgically patent sinuses, only one of five subjects showed any type of sinus penetration. CONCLUSION: The nebulizer and nasal spray devices tested in general showed limited penetration of the sinuses in both normal and postoperative patients. The device showing greatest promise for sinus penetration in normal patients was the vortex nebulizer, with an overall penetration rate in normal patients of 30% in the frontal, 30% in the sphenoid, and 10% in the maxillary. Understanding delivery patterns of topical therapies may be important in evaluating the efficacy of various topical treatment modalities.Wirksamkeit der Empfehlungen: Es ist mit höchstem 'Evidenz'grad belegt, dass die überwältigende Mehrheit der Patienten mit Husten abgeklärt und einer wirksamen Therapie zugeführt werden kann. |

| | |
|---|---|
| **Titel** | **Veränderung von postnasal drip, Reizhusten, Atemwegswiederstand und bronchialer Hyperreagibilität bei Asthma bronchiale durch oszillierende PEP-Behandlung (RC-Cornet®-N) des Nasen-Rachen-Raums (Eine randomisierte, prospektive Double Dummy Studie über 4 Wochen)**<br><br>***Changes of postnasal drip, dry cough, airway resistance and bronchial hyper reactivity of bronchial asthma with oscillating PEP-Care (RC-Cornet®-N) of the neck-nose-throat-area (A randomised prospective double dummy study about 4 weeks) (only in German language available)*** |
| **Autor/Author** | U.H. Cegla;H.-J. Jost; A.Harten |
| **Journal** | Atemwegs- und Lungenkrankheiten, Zeitschrift für Diagnostik und Therapie, Jahrgang 29 Nr.9/2003, S.428-436 |
| **Abstrakt/ Abstract** | Bei dieser randomisierten prospektiven Double-Dummy-Studie gaben 84% der Patienten an, dass ihr Reizhusten durch die Anwendung des RC-Cornet®-N verschwunden sei. 88% der Postnasal-drip Gruppe gaben ebenfalls entsprechende deutliche Verbesserungen der Symptomatik an. Atemwegswiderstand und bronchiale Hyperreagibilität wurden sifnifikant vermindert.<br><br>*In this randomized prospective double-dummy-study 84% of the patients documented that their dry cough is gone after using of the RC-Cornet® N. 88 % of the postnasal drip group confirmed the same improvements of the symptomatic. The resistance of the airways and the bronchial hyper reactivity reduced significantly patients of 30% in the frontal, 30% in the sphenoid, and 10% in the maxillary. Understanding delivery patterns of topical therapies may be important in evaluating the efficacy of various topical treatment modalities.* |

# 5. RC-Cornet® Tracheoset / RC-Cornet® PLUS TRACHEO

| **Titel** | **Bagging und Air Stacking: Ein atemtherapeutischer Ansatz für Patienten in der neurologischen Frührehabilitation (only in German language available)** |
|---|---|
| **Autor/Author** | K. Frank, U. Frank |
| **Journal** | Pneumologie 2011; 65(5): 314-319; DOI: 10.1055/s-0030-1256181 |
| **Abstrakt/ Abstract** | In einem Pilotprojekt wurde untersucht, ob eine adaptierte atemtherapeutische Methode (Bagging) bei Patienten der Frührehabilitation zu verbesserten SPO2 Werten führt. Beim Bagging wird während der Inspirationsphase mit Hilfe eines Beatmungsbeutels zusätzlich Luft in die Lunge gegeben. Der Patient erhält nachfolgend eine manuelle Hustenunterstützung. Es wurden 11 Probanden untersucht, diese erhielten in einem Behandlungszeitraum von 12 Tagen 1–2 × täglich eine Bagging-Anwendung. Es wurden Gruppen- und Einzelfallanalysen gemäß einer Zuordnung in SPO2-Kategorien durchgeführt (Kat. 1: ≤ 90 %, Kat. 2: ≤ 94 %, Kat. 3: > 94 %). Die Bagging-Therapie führte bei allen Probanden zu einer stabilen Erhöhung der SPO2-Werte. Alle Patienten konnten sich im Behandlungsverlauf um mindestens eine Kategorie verbessern. Ein Zusammenhang zwischen Therapieverlauf und Diagnose der einzelnen Patienten bestand nicht. Weitere positive Effekte waren eine Verbesserung der Vigilanz, der Bronchialsekretviskosität und der Schluckfunktion. Die Methode ist leicht zu erlernen und die Materialkosten sind gering, sodass sie gut in klinisch-therapeutische Abläufe zu integrieren ist. |

| **Titel** | **Logopädische Therapie bei fazioskapulohumeraler Muskeldystrophie und myotoner Dystrophie Typ 1 (Curschmann, Steinert) im Erwachsenenalter (only in German language available)** |
|---|---|
| **Autor/Author** | W. Rösler, E. Schwarz, H. Tast, I. Wellinger |
| **Journal** | Neurol Rehabil 2012; 18 (1): 42–54 © Hippocampus Verlag 2012 |
| **Abstrakt/ Abstract** | Bei Patienten mit neuromuskulären Erkrankungen haben neben den im Vordergrund stehenden Dysphagien auch Dysarthrien erhebliche Auswirkungen auf die Lebensqualität und soziale Teilhabe, finden aber wesentlich weniger Beachtung. Zudem bestehen große Unsicherheiten in der logopädischen Behandlung dieser Gruppe vergleichsweise seltener Erkrankungen. Im Gegensatz beispielsweise zum Hirninfarkt ist nicht die Restitution, sondern vielmehr die Optimierung und möglichst langfristige Stabilisierung vorhandener Ressourcen das Ziel, um eine Erleichterung im Alltag und |

| | |
|---|---|
| | bestmögliche Lebensqualität zu erreichen. Hierbei sind die ICF-Komponenten Funktion, Aktivität und Partizipation in der Therapieplanung gleichermaßen zu beachten. Am Beispiel der fazioskapulohumeralen Muskeldystrophie und der myotonen Dystrophie Typ 1 werden einige Zielsetzungen und Grundprinzipien, unter anderem die besondere Bedeutung der Körperhaltung, die Beachtung der Belastbarkeit sowie unterstützende passive und assistive Übungen beschrieben. |

| **Titel** | **Prolongiertes Weaning S2K-Leitlinie herausgegeben von der Deutschen Gesellschaft für Pneumologie und Beatmungsmedizin e.V. (only in German language available)** |
|---|---|
| **Autor/Author** | B. Schönhofer, J. Geiseler, D. Dellweg, O. Moerer, T. Barchfeld, H. Fuchs, O. Karg, S. Rosseau, H. Sitter, S.Weber-Carstens, M.Westhoff, W.Windisch |
| **Journal** | Prolonged Weaning S2k-Guideline Published by the German Respiratory Society |
| **Abstrakt/ Abstract** | Bei Patienten mit neuromuskulären Erkrankungen haben neben den im Vordergrund stehenden Dysphagien auch Dysarthrien erhebliche Auswirkungen auf die Lebensqualität und soziale Teilhabe, finden aber wesentlich weniger Beachtung. Zudem bestehen große Unsicherheiten in der logopädischen Behandlung dieser Gruppe vergleichsweise seltener Erkrankungen. Im Gegensatz beispielsweise zum Hirninfarkt ist nicht die Restitution, sondern vielmehr die Optimierung und möglichst langfristige Stabilisierung vorhandener Ressourcen das Ziel, um eine Erleichterung im Alltag und bestmögliche Lebensqualität zu erreichen. Hierbei sind die ICF-Komponenten Funktion, Aktivität und Partizipation in der Therapieplanung gleichermaßen zu beachten. Am Beispiel der fazioskapulohumeralen Muskeldystrophie und der myotonen Dystrophie Typ 1 werden einige Zielsetzungen und Grundprinzipien, unter anderem die besondere Bedeutung der Körperhaltung, die Beachtung der Belastbarkeit sowie unterstützende passive und assistive Übungen beschrieben. |

| **Titel** | **Die Tracheotomie in der Intensivmedizin Tracheostomy in intensive care medicine** |
|---|---|
| **Autor/Author** | M. Gründling; K. Westphal; C. Byhahn; V. Lischke |
| **Journal** | March 1999, Volume 48, Issue 3, pp 142–156 |
| **Abstrakt/ Abstract** | Die Tracheotomie ist der allgemein akzeptierte Zugangsweg zur Freihaltung der Atemwege bei Langzeitbeatmung. Ob eine „frühe“ Tracheotomie gegenüber der „späten“ Vorteile bringt, ist bisher nicht ausreichend geklärt. Neben der operativen Tracheotomie wird zunehmend die Percutane Dilatationstracheotomie (PDT) in der intensivmedizinischen Praxis eingesetzt. Die derzeit verfügbaren Dilatationsmethoden gestatten gleichermaßen die sichere, komplikationsarme Durchführung einer bettseitigen Tracheotomie auf der |

| | |
|---|---|
| | Intensivstation. Exakte Kenntnisse der Anatomie der Halsregion und des Operationsablaufes sind Voraussetzung für die Durchführung des Eingriffs. Unter Beachtung der Kontraindikationen bieten die Verfahren der PDT Vorteile gegenüber der operativen Tracheotomie. Zur Risikominimierung sind ein sicherer Umgang mit dem Airwaymanagement sowohl bei der operativen Tracheotomie als auch bei PDT und Kenntnisse über die Unterschiede des dilatativen gegenüber dem epithelialisierten operativen Tracheostoma unverzichtbar. Bei den dilatativen Verfahren sollte grundsätzlich eine endoskopische Kontrolle der Prozedur erfolgen.<br><br>*Tracheostomy is one of the oldest surgical procedures and in the past decades has become the method of choice in the management of patients requiring long-term mechanical ventilation. At present, several alternatives exist to conventional surgical tracheostomy, such as the percutaneous dilatational techniques according to Ciaglia (PDT), Griggs (GWDF), and Schachner (Rapitrach). In particular, PDT according to Ciaglia which was introduced in 1985, has been recognized as an equally safe, but less expensive procedure than conventional tracheostomy. Fantoni's translaryngeal percutaneous technique is another new and safe procedure, which was first performed in 1996. Nonetheless, we believe that percutaneous procedures should only be performed by experienced physicians who are well-trained in both endotracheal intubation and mask ventilation. Furthermore, the capacity to perform surgical tracheostomy immediately in case of complications should be given. Only if the contraindications are carefully observed, will these new procedures retain their value and benefit in airway management of long-term ventilated patients.* |

## 6. Impressum / *Imprint*

Trotz gewissenhafter Recherche bei der Erstellung und regelmäßiger Revision kann es zu Abweichungen, Widerlegungen und sonstigen Änderungen der hier veröffentlichten Informationen kommen für die R.Cegla GmbH & Co. KG keine Haftung übernimmt.

Weiterhin möchten wir darauf hinweisen, dass diese Studien nicht als alleinige Entscheidungsbasis verwendet werden sollten.

Despite of a carfully research before publishing and constant reviews is it possible that the published information are different, disproved or includes other deviations for which R.Cegla GmbH& Co. KG is not liable.

Due to this we want to advise you that these information shall not be used as only basis for buying decisions.



Juni, 2018

R.Cegla GmbH & Co. KG

Horresser Berg 1

D-56410 Montabaur

Tel. +49 (0) 2602 9213-0

E-Mail info@cegla.de

www.cegla.de