P272 Does adding telemonitoring to optimised management of chronic obstructive pulmonary disease (COPD) reduce hospital admissions? Randomised controlled trial

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Introduction: Previous trials of telemonitoring in COPD have been confounded by additional supportive clinical care in the intervention group. It is unclear if telemonitoring alone will improve clinical outcomes

Aim: To determine if telemetrically supported self-monitoring of COPD prevents hospital admissions when both groups receive optimised care.

Trial design: Researcher-blind RCT.

Setting: UK primary care.

Methods: Patients with a COPD admission in the previous year were centrally randomised to telemetric or normal monitoring. The primary outcome, assessed at 1 year, was time to first hospital admission with a COPD exacerbation. Other outcomes included number of days in hospital, deaths and health-related quality of life (St George’s Respiratory Questionnaire (SGRQ)).

Results: We randomised 256 patients (128 telemonitoring) baseline characteristics were similar. Using an intention-to-treat analysis, there was no difference in time to admission between the groups (adjusted hazard ratio for admission (reference=tele-group) 1.04 (95%CI 0.73 to 1.50). 61 patients in each group had an admission. There was no significant difference in the mean number of admissions/person/year: 1.2 (SD 1.0), control: 1.1 (SD 0.6); bed-days (tele-group: 9.4 (SD 19.1) vs usual 8.8 (SD 15.9)); deaths (tele-group: 16, control 21; p=0.38) or SGRQ at 1 year (mean difference: 1.5 (-1.4 to 4.5))

Conclusion: When both groups received optimised care, telemonitoring did not reduce the time to a hospital admission or increase quality of life.

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P2727 Multicenter COPD registry for quality improvement and comparative effectiveness research

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Introduction: In 2011, we conducted a comprehensive asthma survey in Latin America to explore realities of living with asthma and identify unmet needs in asthma management. The Latin America Asthma Insight and Management (LA AIM) survey was modeled on similar programs in the United States, Europe and Canada, and the Asia-Pacific region.

Methods: Face-to-face interviews lasting approximately 35min were conducted with respondents in a national probability sample. The survey was included 2000 participants (400 participants in Latin America (Argentina, Brazil, Mexico, Venezuela) and Puerto Rico) (20% International and the Environment Group Initiative, The University of Edinburgh, Edinburgh, United Kingdom.

Aim: To determine if telemetrically supported self-monitoring of COPD prevents hospital admissions when both groups receive optimised care.

Trial design: Researcher-blind RCT.

Setting: UK primary care.

Methods: Patients with a COPD admission in the previous year were centrally randomised to telemetric or normal monitoring. The primary outcome, assessed at 1 year, was time to first hospital admission with a COPD exacerbation. Other outcomes included number of days in hospital, deaths and health-related quality of life (St George’s Respiratory Questionnaire (SGRQ)).

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Conclusion: When both groups received optimised care, telemonitoring did not reduce the time to a hospital admission or increase quality of life.

ISRCTN number: 96634935

Funding: Chief Scientist’s Office of Scottish Government.

P2720 Cough, active smoking ever, smoking history of >10 packyears and wheezing/chest tightness should prompt COPD suspicion in cardiac patients who remain symptomatic despite adequate management

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Background: Coronary heart disease (CHD) and chronic obstructive pulmonary disease (COPD) share common risk factors and often coexist. Dyspnea, effort intolerance and chest tightness in CHD patients are readily attributed to cardiac disorder while COPD passes unnoticed. Proper COPD management optimizes patient’s outcome.

Aim: The aim of our study was to determine key features from history and physical examination that should raise COPD suspicion in persistently symptomatic cardiac patients.

Material and methods: Patients were recruited with respect to the following inclusion criteria: angiographically confirmed CHD, adequate cardiac management, ability to visit study site, expressed informed consent for study participation. Subjects were evaluated for: demography, smoking, respiratory complaints (modified ECRHS questionnaire), airflow limitation (spirometry accompanied by reversibility test if applicable). COPD diagnosis was based on clinical presentation, history and post- bronchodilator FEV1/FVC<0.7.

Results: Among 206 subjects eligible for the study 33 (16%) were found to have COPD. COPD vs. non-COPD subjects did not differ in age, sex, BMI, waist circumference and tobacco exposure in general. Active smoking ever (OR 5.45, 95%CI 1.24-23.9), >10 packyears (OR 4.28, 95% CI 1.57-11.7), cough (OR 8.65 95%CI 3.16-23.6) and wheezing/chest tightness (OR 3.38 95%CI 1.51-7.58) significantly increased COPD risk.

Conclusion: Longstanding history of active smoking ever, cough and wheezing/chest tightness in persistently symptomatic cardiac patients should raise the suspicion of concomitant COPD.
In outpatients with COPD, the baseline CAT score showed a strong predictive value of exacerbations in the following six months. It also provided modest prediction of exacerbations for time to first exacerbation. The baseline CAT score categorised into four severity groups showed a strong predictive value for time to first exacerbation (hazard ratios of 1.0, 1.53, 2.08 and 3.41 respectively). CAT score category, how-ever, had a modest predictive ability for at least one exacerbation (AUC=0.64).

P2732
Sleep-related breathing disorders in patients with schistosomal cor-pulmonale
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Schistosomiasis has long been an endemic disease in Egypt and an important cause of pulmonary hypertension.

Objectives: We aimed to investigate the clinical and polysomnographic features of sleep-related breathing disorders (SRBD) in patients with schistosomal cor pulmonale and to evaluate their effects on pulmonary hemodynamics.

Patients and methods: We studied 10 stable patients with schistosomal pulmonary hypertension (mean age was 43.7) and 10 healthy volunteers matched. All underwent overnight polysomnography.

Results: The mean AHI in patients group was 20/h while in the control group it was 3/h. 80% of the patients were found to have an AHI >10/h and 60% had moderate to severe sleep apnea (AHI ≥ 15/h). In addition, the majority of the patients (80%) spent > 30% of the night with an arterial oxygen saturation < 90%. The risk of severe exacerbations was higher with worsening category of CAT score (p=0.004, adjusted relative risks: 1.0, 1.26, 1.33 and 1.45 respectively). The un categorised CAT scores, used as a continuous variable, found predictions of similar magnitude.

In outpatients with COPD, the baseline CAT score showed a strong predictive value for time to first exacerbation. It also provided modest prediction of exacerbations in the following six months.

P2734
Measuring red blood cell oxygenation in vivo using hyperpolarized 129Xe MRI
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Introduction: Red blood cell (RBC) oxygenation plays an important role in cell survival. However, measuring this parameter in deep tissues is difficult. We report a method of detecting RBC oxygenation in vivo using MRI chemical shift (CS) hyperpolarized (HP) 129Xe dissolved in RBCs explored previously in vitro (Mag Res Med 43;4(91) 2000).

Methods: 400mL of HP 129Xe mixed with 600mL N2 was delivered to 3 healthy volunteers who inhaled the gas and held their breath. Spectroscopy was performed on a 3T Philips Intera every 3 seconds for the length of the breath hold. CS was extracted from fits to the spectra. Surrogate oxygenation was measured using an SpO2 monitor.

Results: Example spectra from one volunteer early(red) and at end of breath hold(blue) are shown in Fig 1(left). The CS change between the tissue/plasma and the RBC peak are plot as a function of time(green) in the panel right along with measured SpO2(blue). A decrease in the separation between these two peaks is seen over the course of the breath hold corresponding with a measured decrease in SpO2. Similar trends are seen in data from all subjects.

Discussion: The CS decrease with breath hold time correlates with in vitro data showing CS decrease with RBC deoxygenation. To our knowledge, this is the first demonstration in humans of the effect of RBC oxygenation on the CS of dissolved 129Xe. Localisation of this technique may provide insight into regional RBC oxygen non invasively.

Background: Recent advances in molecular genetics have opened new perspectives in the definition of pathogenic mechanisms of SIDS. Several studies, during the past decade, identified polymorphisms in the serotonin transporter (5HTT), hydroxytryptamin transporter-linked polymorphic region, and Sln2, intron 2 VNTR), the promoter region of MAOA (monoamine oxidase A), and DAT in an Italian SIDS population. ALTE patients, IALTE (idiopathic ALTE) and controls.

Methods: We enrolled 76 infants with an history of Apparent Life Threatening Event, distinguished in Idiopathic ALTE (IALTE) and Non Idoiplastic ALTE (ALTE) by: clinical, diagnostic and therapeutic data (12 channels polysomnography E-Series Compumedics). Genotypes and allelic frequencies of DAT, MAOA and SHTT were determined in ALTE and IALTE infants compared with data obtained from The First Shrihart Hospital.

Results: No association was found between DAT polymorphism and ALTE/IALTE groups either in the genotype (p=0.25; p=0.112) nor in the allelic frequency (p=0.94; p=0.88). The comparison of MAOA genotypes and allelic frequency between ALTE and control group was not significant, on the opposite the comparison between IALTE and control group was statistically significant for the genotypes (p=0.09) and a tendency for allele (p=0.036). Analysis of SHTT polymorphisms in IALTE remarked the pathogenetic role of L/L genotype (P<0.0001) and L allele (P=0.0007) as previously demonstrated in SIDS.
**P2735**
**Circulating collagen indices indicative of disease severity in pulmonary arterial hypertension**
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Procollagen deposition occurs in exhaled pulmonary arterial hypertension (PAH) lungs. Biochemical monitoring of collagen synthesis may provide a non-invasive method of determining vascular remodeling. However, there is lack of data regarding circulating procollagen indices in PAH. We obtained circulating levels of carboxy-terminal of procollagen type III (PIIINP) and amino-terminal telopeptide of collagen type I (CTTP), matrix metalloproteinase-9 (MMP-9) and tissue inhibitor of metalloproteinase-1 (TIMP-1) from 87 PAH subjects and 37 age- and gender-matched controls (Baylor PH Center). Serum was separated and stored at -80°C. CTTP, MMP-9 and TIMP-1 levels were measured by ELISAs. PIIINP was measured by antibody radioimmunoassay. PAH patients had elevated PIIINP, CTTP, MMP-9 and TIMP-1 levels suggesting active collagen metabolism (Table 1). PIIINP levels were higher in WHO FC III-IV as compared to WHO FC I-III PAH patients (p=0.011). PIIINP levels negatively correlated with six-minute walk distance (R=0.3, p=0.008), and positively correlated with right atrial pressure (R=0.35, p=0.002) and BNP levels (R=0.25, p=0.02).

Clinical characteristics and biomarker levels in PAH patients

<table>
<thead>
<tr>
<th>Age (yrs)</th>
<th>Gender (F, %)</th>
<th>Controls (n=39)</th>
<th>PAH (n=79)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>49.1±14</td>
<td>33 (89)</td>
<td>38 (90)</td>
<td>0.34</td>
<td></td>
</tr>
<tr>
<td>BSA (cm²)</td>
<td>1.79±0.24</td>
<td>1.83±0.19</td>
<td>0.36</td>
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<tr>
<td>Pulse pressure (mm Hg)</td>
<td>36.6±17</td>
<td>37.6±17</td>
<td>0.82</td>
<td></td>
</tr>
<tr>
<td>6MWD (meters)</td>
<td>46.6±63</td>
<td>412±106</td>
<td>0.005</td>
<td></td>
</tr>
<tr>
<td>BNP (ng/ml)</td>
<td>19±9.1</td>
<td>156±202</td>
<td>0.002</td>
<td></td>
</tr>
<tr>
<td>PIIINP (ng/ml)</td>
<td>3.80±0.92</td>
<td>5.2±1.88</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>MMP-9 (ng/ml)</td>
<td>291±51.1</td>
<td>478±292</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>TIMP-1 (ng/ml)</td>
<td>128±6.3</td>
<td>202±63</td>
<td>0.001</td>
<td></td>
</tr>
<tr>
<td>CTTP (ng/ml)</td>
<td>2.20±1.1</td>
<td>4.03±0.33</td>
<td>&lt;0.001</td>
<td></td>
</tr>
</tbody>
</table>

Circulating procollagen markers may provide a novel non-invasive method of documenting active collagen synthesis reflective of severe disease in PAH.

**P2736**
**Development of an intervention algorithm in telemetrically supervised adaptation of positive airway pressure therapy for OSAS**
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Introduction: The acceptance of positive airway pressure therapy (PAP) is a major clue to successful OSAS therapy. Telemedicine is a novel tool to supervise patients during the first month of telemetrically supervised PAP adaptation.

Methods: After mask adaptation and explanation of the PAP devices (ResMed 39), newly diagnosed OSAS patients were equipped with telemedicine (ResTraxx Online™, ResMed) for the first month of therapy. The automatically downloaded S9), newly diagnosed OSAS patients were equipped with telemedicine (ResTraxx Online™, ResMed) for the first month of therapy. The automatically downloaded data was downloaded from the telemedicine device to a computer and saved. Data were reviewed and evaluated. Technical problems, number and duration of phone calls and CPAP use information were analysed.

Results: During the study period, 73 OSAS patients received telemedicine for a total of 2045 nights. Minor technical problems with data transmission for 1 to 3 nights occurred in 12(16%) patients. The average PAP use was 4.2±0.4L/s. Technical problems, number and duration of phone calls and CPAP use information were analysed.

Controls | PAH | p value
---|---|---
Age (yrs) | 49.1±14 | 47.6±14 | 0.34
Gender (F, %) | 33 (89) | 79 (90) | 0.34
BSA (cm²) | 1.79±0.24 | 1.83±0.19 | 0.36
Pulse pressure (mm Hg) | 36.6±17 | 37.6±17 | 0.82
6MWD (meters) | 46.6±63 | 412±106 | 0.005
BNP (ng/ml) | 19±9.1 | 156±202 | 0.002
PIIINP (ng/ml) | 3.80±0.92 | 5.2±1.88 | <0.001
MMP-9 (ng/ml) | 291±51.1 | 478±292 | <0.001
TIMP-1 (ng/ml) | 128±6.3 | 202±63 | 0.001
CTTP (ng/ml) | 2.20±1.1 | 4.03±0.33 | <0.001

**P2737**
**Safety profile and pharmacokinetics of an inhaled GATA-3-specific DNAzyme in a first-in-man study in healthy subjects**
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SB010 (a nebulisation solution of the human GATA-3-specific DNAzyme hgd40) has been developed and preclinically characterized as an intended treatment of Th2-driven asthma. DNAzymes are single-stranded catalytic DNA molecules that specifically bind and cleave target mRNA sequences. Aim of the present study was to investigate safety, tolerability and pharmacokinetics of orally inhaled single ascending doses of SB010 in a First-in-Man Phase I clinical trial. The study was performed as a randomized, double-blind, placebo controlled, parallel group (per dose level) dose escalation study in healthy male Caucasian subjects (18-45 years). SB010 was applied as nebulized solution via a controlled breathing system (AKTA2 APEXNEB®) in 6 dose levels ranging from 0.4 – 40 mg. Adverse events, vital signs, clinical chemistry, hematology, uric acid, ECG, pulmonary function testing, body temperature, and overall tolerability were assessed. Plasma concentrations were analyzed using a hgd40-specific hybridization ELISA system. All doses were well tolerated, no serious or severe adverse events and no dose limiting effects were observed. Occasional adverse events (such as headache or cough) were of minor clinical relevance and were fully reversible during the study period. Maximum plasma concentrations of hgd40 were detected within the highest dose group at one hour after administration (29.2 µg/ml ± 20.6) and hgd40 was no longer detectable at time point 12 hours after administration. Overall, inhaled SB010 turned out to be well tolerated after single inhalative exposure in healthy male subjects and is now under evaluation in subsequent clinical studies.

**P2738**
**Repeatability of the endurance shuttle walk test in COPD**
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The aim was to evaluate the repeatability of the endurance shuttle walk test (ESWT) measured within the same day, within the same week and a week apart. Methods: Individuals diagnosed with COPD were recruited. Participants were asked to perform two incremental shuttle walk tests (ESWT) for predicting the walking intensity for the ESWT. ESWT 1 (E1) and ESWT 2 (E2) were performed on the same day, 30 minutes apart. ESWT 3 (E3) was performed within a week from E1 and ESWT 4 (E4) was performed one week after E1. Heart rate (HR) (Polar RS800CX, Polar, Finland) and dyspnoea (Borg scale 0-10) were measured before and after each ESWT. Duration walked in each ESWT was measured and the corresponding walking distance was calculated. The repeatability of the four ESWTs was analysed using repeated measures ANOVA.

Results: Twenty-two participants (mean ± SD age 71.6±6 years; FEV1% predicted 54.2±4%; TLC 12.2±2.1% completed the study. The mean durations of E1 to E2 were 368±203s, 371±185s, 360±213s and 367±223s respectively, with no time effect (F=0.18, p=0.79). The corresponding distances walked in E1 to E2 were 474±300m, 478±267m, 511±349m, 487±538m respectively, with no time effect (F=1.36, p=0.65). The percentage predicted VRmax at the end of E1 were 79±6%, 80±11%, 82±9%, 80±5% respectively, with no significant time effect (F=1.94, p=0.13).

Conclusion: There was no evidence of a learning effect when an ESWT was repeated within one day, within one week and a week apart, showing that the ESWT is repeatable in people with moderate COPD.
P2740
Prevention of RSV infection in infants from the high-risk groups in Moscow: The first season’s results
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Aim: Analysis of efficacy and safety of immunization with palivizumab in infants from the high-risk groups of severe respiratory syncytial viral (RSV) infection carried out during 2012 infection season in Moscow.

Methods and materials: Immunization against RSV infection with palivizumab was conducted for the first time in six Moscow hospitals from January to May 2012. The total number of infants immunized was 156 aged from 15 days to 1 year 11 months. Patients received from 1 to 4 shots with treatment-free interval 30±5 days: 1 infant was immunized four times, 139 – three times, 9 children – twice, 7 children – once. The reasons for discontinuation of immunization after 1 and 2 shots were not connected to medical conditions. 139 (89.1%) of all infants were premature, including 42 (26.92%) - with extremely low birth weight, 83 (53.21%) - with bronchopulmonary disease, 19 (12.18%) - with congenital heart diseases. Efficacy of immunization was estimated on a basis of the average monthly frequency of lower respiratory tract infections and hospitalization within three months before and three months during prophylaxis. A frequency of adverse events was used for safety analysis.

Results: Immunization with palivizumab led to decrease of the average monthly frequency of lower respiratory tract infections (from 0.064 to 0.014) and hospitalization (from 0.048 to 0.011). The following adverse events were reported: short-term, low-grade fever, anxiety, rhinitis, upper respiratory tract infection, gastroenteritis. There were no serious adverse events reported during prophylaxis.

Conclusions: Prophylaxis of RSV infection with palivizumab in infants from the high-risk groups is safe and effective.

P2741
Association of airway bacterial load with inhaled corticosteroid dosage in stable COPD
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Inhaled corticosteroids (ICS) are commonly used in COPD, either alone or in combination with bronchodilators to reduce exacerbation frequency, but may also increase risk of pneumonia. Lower airway bacterial colonisation is often present in stable COPD and may predispose to pneumonia. We investigated the relationship between airway bacterial load and ICS dosage in stable COPD patients.

We quantified typical bacterial load using a validated PCR (for H. influenzae, S. pneumoniae, M. catarrhalis) from the sputum of 47 stable COPD patients positive for at least one of these species. Patient characteristics: Mean(SD) age 71.6(8.0) years; Male gender 64%; Current smoker 34%; FEV1 49.0(18.4) predicted. Median (IQR) beclomethasone-equivalent dosage was 2000 (640-2000) μg daily. Higher airway bacterial load was correlated to higher ICS dosage (corrected for beclomethasone equivalence) in a univariate analysis; r=0.382; p=0.008 (Fig. 1). This relationship remains significant in a multivariate analysis including age, smoking status and FEV1 % predicted (p=0.022).

Conclusions: Preventive effect of ICS therapy is associated with higher airway bacterial load and may therefore play a part in increasing susceptibility to pneumonia in COPD.