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0969

Development Process of a New Quality of Life (QoL) Questionnaire Suitable for Patients with Chronic Respiratory Failure

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Although the St George's Respiratory Questionnaire recently showed sensitivity to changes in hypercapnic COPD (Meecham-Jones, D.J. Am J Respir Crit Care Med 1995; 152:538-44), at present there is no QoL questionnaire specific for respiratory failure. We identified 152 items relevant to severe respiratory disease. These were administered to 92 patients affected by COPD (56 males, 19 females) or kyphoscoliosis (5 males, 12 females): 79 were on LTOT; 34 had overnight mechanical ventilation (IPPV). Mean age 65 ± 8 (sd) yrs, FEV1 0.90 ± 0.46 L. They also indicated their perceived overall and respiratory health using two five-point scales. To reduce the number of items, we deleted those influenced by the underlying disease or treatment (Chi squared with Fisher's exact test p < 0.05), age (Spearman's rho p < 0.05) or sex (Chi squared with Fisher's exact test p < 0.05), and those that did not correlate with perceived health (Spearman's rho p > 0.05). Of the remaining 46 items, 3 were present in two forms (e.g. Getting dressed makes me breathless/Because of breathlessness I am not dressing myself as I would like to); we chose the form that better correlated with perceived health. Then we removed 10 items with either very low (< 20%) or very high (> 80%) response rates. The resulting 33 items were verified for repeatability over 2 weeks: only 24 items remained in the final questionnaire. The repeatability of the 24-item questionnaire was high (r = 0.95). We conclude that this questionnaire is repeatable and irrespective of underlying disease, treatment, age and sex, and correlates well with perceived health.

0970

Cross-Sectional Analysis of a New Questionnaire for the Quality of Life (QoL) in Chronic Respiratory Failure

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A 24-item questionnaire specifically designed for severe respiratory diseases was administered to 92 patients (61 males, 31 females) who were receiving LTOT (n = 79) or overnight mechanical ventilation, some via a tracheostomy (n = 13) and others through a nasal mask (n = 21). Their mean age was 65 years (range 39-78), mean FEV1 36% ± 15%; 6-minute walking distance (6-MWD) 269 ± 89 m. The patients also completed the Medical Research Council (MRC) Dyspnoea Scale, a scale for depression (QD), one for anxiety (STAI), the St George's Respiratory Questionnaire (SGRQ) and the Sickness Impact Profile (SIP). The new questionnaire's score correlated weakly with some patho-physiological measures, such as FEV1/FVC, 6-MWD, the 6-MWD oxygen flow rate, and the oxygen flow rate prescribed at rest. Conversely, it correlated better with MRC, QD, STAI, SGRQ and SIP scores.

	r-squared	p		r-squared	p
FEV1/FVC	0.08	< 0.02	QD	0.59	< 0.0001
6-MWD metres	0.09	< 0.01	STAI	0.19	< 0.0001
6-MWD O2 flow	0.10	< 0.005	SGRQ total	0.71	< 0.0001
Rest O2 flow	0.12	< 0.003	SIP total	0.50	< 0.0001
MRC	0.23	< 0.0001			

The repeatability of the new questionnaire was measured in 14 patients over 15 days. The r value was 0.95 (95% CI 0.83-0.98) and the coefficient of variation was 15%. We conclude that this questionnaire is a valid and repeatable measure of impaired health in severe respiratory diseases. Therefore, it could be a useful disease-specific measure of QoL.

0971

Quality of Life and Hospital Re-Admission in COPD

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Quality of Life (QOL) in 266 patients admitted to hospital with an exacerbation of COPD, was assessed by St George's Respiratory Questionnaire (SGRQ) [1]. Information on re-admission or death within 12 months, nebuliser provision at discharge and provision of domiciliary oxygen was collected. Mean age of patients was 68 years and 53% were male. Mean FEV was 1.0 SD 0.5, mean FVC 2.1, SD 0.8. Higher (worse) scores on the SGRQ were significantly related to re-admission for COPD or death in the next 12 months (Diff = 5% 95% CI Diff 1.6% to 8% p = 0.003). Re-admission was not related to gender, age or pulmonary function. 158 patients did not have a home nebuliser before admission. Of these, 14 were provided with a home nebuliser at discharge. Patients provided with nebulisers had significantly worse SGRQ scores (p < 0.001) and worse FVC (p < 0.01). The 41 patients with domiciliary oxygen on admission did not differ in

SGRQ or spirometry. Logistic regression analysis of SGRQ subscales showed that the Impact subscale of the SGRQ was the best predictor of hospital re-admission and nebuliser provision. Symptom and Activity scores were not significant predictors when Impact scores were controlled for. Women did not differ from men in Symptom scores but differed markedly in Activities and Impact scores. We conclude that QOL scales which measure patient distress and coping, can predict clinical outcomes independent of physiological measures of disease severity.

[1] Jones PW, et al. A self-complete measure of health status for chronic airflow limitation. The St. George's Respiratory Questionnaire. American Review of Respiratory Disease 1992; 145: 1321-1327.

0972

Comparison of Quality of Life in Sarcoidosis and Idiopathic Pulmonary Fibrosis

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Quality of Life (QoL) in diffuse interstitial lung diseases has not been studied, although they have a chronic debate course. In this study two disease with different natural course, sarcoidosis and IPF were compared.

Material and method: We studied 30 patients with sarcoidosis (13M, 17F) aged 23-63 years and 12 with IPF (9M, 3F), aged 41-71 years. The modified Medical Research Council (MRC), the BORG and the Oxygen Cost Diagram (CO₂COST), dyspnoea scales, 2) the St. George's Respiratory Questionnaire (SGRQ) 3) the general health questionnaire of well-being (QWB), and 4) the Anxiety and Depression scale (Anx-Depr) were used to access dyspnoea and QoL. In addition, spirometry, lung volumes, diffusion capacity and arterial blood gases (ABGs) were measured.

The results are shown in the table.

	BORG (0-100)	MRC (0-4)	CO ₂ COST (100-0)	QWB (1-0)	ANX (< 8 to > 10)	DEPR (< 8 to > 10)	SGRQ (0-100)
Sarc	1 ± 0.9	1.7 ± 1.3	68 ± 24	0.8 ± 0.2	9.4 ± 4.8	5.7 ± 4.3	21 ± 15.2
IPF	2 ± 1	6.4 ± 9.6	60.8 ± 24	0.7 ± 0.2	6.3 ± 5.3	5.1 ± 4.5	31.8 ± 15
p	0.007	0.02	NS	NS	NS	NS	0.03

We conclude that in the studied population QoL was mildly affected in sarcoidosis but significantly altered in the patients with IPF.

Rehabilitation programmes: Techniques and schedule

0973

Dyspnoea During an Incremental Ergometer Test and Respiratory Muscle Load

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Background: In this study the correlation between dyspnoea and load on the ventilatory muscles was assessed. Both inspiratory and expiratory muscle load were of our interest. This was done in patients with obstructive pulmonary diseases during an incremental maximal exercise test. A subdivision was made between patients with or without a ventilatory exercise limitation. The first was defined as an increase in PaCO₂ during exercise.

Methods: Fifty patients with a wide range of obstructive pulmonary diseases (FEV1 % pred.: 66.1% ± 28.8) performed an incremental cycle ergometer test. During the test dyspnoea (Borg), oesophageal pressures, mechanical load on the ventilatory muscles (time tension index (TTI)) and minute ventilation were measured. The amplitude of pleural pressures (Pi + Pe)_{act} generated at Wmax was multiplied with the breathing frequency (= PFP, indication of the muscle load). PFP% was calculated from: frequency * (Pi_{act} + Pe_{act}) / (Pi_{max} + Pe_{max}). Linear regression between V_E and PFP at Wmax was calculated for both groups. The slopes of these relationships give an impression of the length-tension-inappropriateness. When there was a difference in slope it was assessed whether this led to a difference in Borg score for dyspnoea be-

Table 1. Correlations (r) and p-values between Borg dyspnoea (Bd) and TTI_i, TTI_e, PFP and PFP%, none of the correlations were significant.

Bd with:	TTI _i	TTI _e	PFP	PFP%
Total (N = 50)	r = -0.2272	r = 0.0614	r = 0.1507	r = -0.0013
Vent. lim. (N = 22)	r = -0.1467	r = 0.0652	r = 0.1922	r = 0.1741
Nvent. lim. (N = 28)	r = -0.3143	r = 0.0619	r = 0.1124	r = -0.1396

tween the two groups. Correlations between the changes in TTI_i, TTI_c, PFP, PFP% and Borg dyspnoea for both groups were calculated.

Results: The slope of V_E/PFP of the non ventilatory limited group was 0.17 L/kP (p = 0.007). The slope of V_E/PFP for the ventilatory limited group was 0.01 L/kP (p = 0.7). The difference between the slopes (0.16) was highly significant (c.i. (0.159-0.161). However there was no difference between the Borg score for dyspnoea between those groups (mean Borg vent. lim.: 5.9 ± 2.6; mean Borg not vent. lim.: 5.9 ± 2.1; p = 0.945). The change in TTI_i was 0.04 ± 0.05 for the ventilatory limited group and 0.07 ± 0.07 for the non ventilatory limited group, which was not significant. The change in TTI_c was 0.08 ± 0.08 and 0.06 ± 0.07 for the ventilatory and the non ventilatory limited group respectively and was also not significant.

Conclusions: The sensation of dyspnoea during exercise in patients with obstructive lung disease, did not correlate with parameters of length tension inappropriateness in respiratory muscles. Other parameters of ventilatory muscle load did also not correlate with Borg score for dyspnoea.

0974

Peripheral Muscle Force is Related to Perceived Quality of Life in COPD Patients

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Perceived quality of life (QoL) is a multidimensional measure. To evaluate the factors that contribute to QoL in COPD, we evaluated 59 patients, (FEV₁ 44 ± 15%) selected for pulmonary rehabilitation. Pulmonary function, respiratory muscle strength, peripheral muscle strength, exercise capacity and QoL, as assessed by the Chronic Respiratory Disease Questionnaire (CRDQ), were measured. Until now 32 patients completed a three month follow up period. After randomization, 14 of these patients received medical treatment only and 18 were included in a rehabilitation program. Single correlation analysis was performed on the initial data and on the changes after three months. At the initial testing, only Mastery correlated significantly with FEV₁ (%pred) (r = 0.35 p < 0.01). Mastery (r = 0.36 p < 0.01), Fatigue (r = 0.37 p < 0.01) and Emotion (r = 0.26 p < 0.05) as well as the total score on the CRDQ (r = 0.32 p < 0.05) correlated significantly with initial Quadriceps force (QF). Changes (Δ) in QoL were not correlated with ΔFEV₁, but correlated significantly with ΔQF (see Table 1). No correlation was detected with other variables.

Table 1: Single correlation coefficients between ΔQF versus Δdimensions in QoL of the CRDQ

	ΔDyspnea	ΔMastery	ΔEmotion	ΔFatigue	ΔTotal
ΔQF	0.38*	0.53**	0.40*	0.33 [◇]	0.46**

*p < 0.05. **p < 0.01. [◇]p = 0.07.

In conclusion, perceived quality of life appears to be linked with peripheral muscle force in COPD patients. Moreover, change in peripheral muscle force is the only factor significantly correlated to altered QoL. Consequently, peripheral muscle training may be an important tool in improving QoL in COPD patients.

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0975

Change in Lower Limb Muscle Strength Contributes to Altered Six Minute Walking Distance in COPD

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It has been shown previously that peripheral muscle weakness is related to exercise intolerance in COPD (Gosselink *et al* Eur Respir J 1995; 8: 127s). Causality of this relationship was examined by performing 3 month follow-up measurements in 17 patients (FEV₁ 46 ± 14%) receiving optimal medical treatment only. Pulmonary function, quadriceps force (QF), handgrip force (HF), inspiratory muscle strength (P_Imax), 6 minute walking test (6 MWD), and maximal cycle ergometry (W_{max}, V_O₂max) were performed at the onset of the study and after 3 months. On the average the measured variables did not change over this period of time. However, individual changes (Δ), expressed as % change from the initial value, were present in positive and negative direction, standard deviation of Δ's being ≈14% for all variables. Significant correlations were present only between ΔQF and Δ6 MWD (r = 0.60 p < 0.02). Such correlations were not present with ΔV_O₂max or ΔW_{max}. Neither was there a correlation between Δ6 MWD and ΔHF or ΔP_Imax. In stepwise multiple regression analysis, ΔQF was significantly related to Δ6 MWD (partial r² = 0.36 p = 0.02). Changes in FEV₁ explained another 12% (p = 0.13) of the variation in Δ6 MWD. In conclusion, change in quadriceps force is an important contributor to altered 6 MWD, in moderate to severe COPD patients. This supports the idea that quadriceps force is causally related to 6 MWD. Efforts in rehabilitation of COPD should be directed towards improvement of lower limb muscle force in order to improve functional exercise capacity.

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0976

Impact of Combined Upper and Lower Limb vs Lower Limb Training in Dyspnea Perception, Hospitalization and Quality of Life in Severe COPD

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Objective: Comparing combined upper and lower limbs (Group I) vs lower limbs (Group II) training in severe COPD patients.

Material and methods: From June 1993 to March 1995, 28 stable COPD patients were randomized in 2 groups: 14 patients (Group I) with combined training: (Mean and SD) Age 63.1 (9.4) years, FEV₁ (L) 0.93 (0.38), FEV₁/FVC 0.46 (0.16), DLCO (ml/mmHg/min) 18.2 (5.1), BMI (kg/m²) 24.7 (4.6); and 14 patients (Group II) with lower limbs training: Age 66.1 (9.2), FEV₁ 1.08 (0.38), FEV₁/FVC 0.42 (0.14), DLCO 16.5 (6.3), BMI 23.3 (4.3).

All patients performed, before and after training, a maximal incremental exercise test with V_O₂ determination and endurance tests for lower limbs (12WT) and upper limbs (6ULT). Both groups were trained above 75% of initial maximal load, during 8 weeks. Group I underwent non supported upper limbs + lower limbs training.

Results:

	Group I			Group II		
	PRE	POST	p	PRE	POST	p
P _I max (cmH ₂ O)	71 (16)	82 (12)	<0.0001	75 (15)	80 (14)	<0.05
P _E max (cmH ₂ O)	93 (28)	106 (25)	<0.0001	104 (31)	112 (28)	<0.01
12WT (m)	706 (218)	917 (208)	<0.0001	674 (128)	912 (126)	<0.0001
QOL Score*	75 (25)	107 (17)	<0.0001	87 (30)	112 (18)	<0.0001
Hospital [§]	11.5 (20)	0.7 (2.6)	<0.0001	20.2 (16)	1.6 (3.3)	<0.0001
W _{max} (kgm)	357 (162)	464 (182)	<0.002	411 (162)	460 (136)	NS
6ULT [♡]	139 (46)	275 (60)	<0.0001	167 (58)	166 (58)	NS
V _O ₂ AT (ml)	7.7 (3.9)	9.5 (3.1)	<0.0001	8.7 (3.7)	8.4 (3.3)	NS
Borg Score	2.5 (1.8)	0.8 (1)	<0.0001	2.2 (1.9)	1.9 (1.7)	NS

*Quality of life score, [§]Hospitalization (number of days/patients/month), [♡]6 min. upper limbs test (upper limbs movements/6 min)

Conclusion: our results suggest that both conventional and combined training improve quality of life, reduce number of hospitalizations and increase P_Imax and P_Emax. Combined training additionally improves upper limbs endurance, dyspnea scores, maximal work and AT onset. We recommended combined training in severe COPD as part of integral rehabilitation program.

0977

Home Endurance Training: Multiple Outcomes of a Trial

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Aim of the study is to evaluate the outcomes of the enrolment of COPD subjects in a rehabilitation programme. The evaluation is focused on: 1) feasibility, 2) patients' compliance, 3) its effects on exercise capacity and lower limbs muscle fibre composition. **Subjects:** 22 COPD patients were enrolled (age 65.36 ± 9.13, FEV₁ 48.4 ± 9.1% of predicted). The need of exercise conditioning was checked by symptom scoring, lung function testing and exercise testing.

Methods: All the subjects underwent lung function testing at rest, exercise testing with measure of maximal O₂ uptake (V_O₂ max), maximal ventilation (V_E max) and arterial lactates. Then a specimen of skeletal muscle (right vastus lateralis) was obtained by needle biopsy technique. Samples were immediately frozen plugging them into isopentane cooled over liquid nitrogen, and stored at -24 °C until the analysis. Each sample was analyzed by electrophoretic method for heavy chains myosin isoforms in order to determine the composition in type I, IIA and IIB fibres. Each patients started a programme focused on controlled endurance training: the programme lasted at least three months and was performed at home. Patients' compliance was monitored by a daily diary. The patients who met what expected, in absence of rehacerbations or other complications, performed exercise testing and quadriceps biopsy again.

Results: 1) 5 patients only completed the programme (22%). A minority of subjects dropped out because of other pathologies or severe rehacerbations of the pulmonary disease, the majority because of a low compliance. 2) The trained patients showed a change in V_O₂max: 1080.4 ml/min ± 290.8 before (b) and 1183 ± 431 ml/min after training (a), in V_Emax: 44.6 ± 11.8 (b) and 39.6 ± 13.7 and in lactates at the end of the exercise test: 3.93 mmol/l ± 1.6 (b) and 2.67 ± 1.1 mmol/l (a). Other resting and exercise functional data did not change. 3) Muscle fibres showed an increase of type I: 47% ± 21 (b) and 54% ± 18 (a) and a reduction in type IIB: 14.3 ± 7.4 (b) and 8.5 ± 3.6 (a), while type IIA was unchanged: 38.7 ± 13.2 (b) and 37.4 ± 8.6 (a).

Conclusions: 1) Rehabilitation programmes planned for a long period of home self management seem to have a low percentage of positive outcome: better selection of the patients and efficient home care health service as necessary. 2) Even though the sample size didn't allow to determine the statistical significance of the results, the training programme appears to modify muscle composition toward a more oxydative metabolism, in accordance with a lower lactate production and a lesser maximal minute ventilation during exercise.