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Outcomes of pulmonary rehabilitation for COPD in older patients: A comparative study.

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Running head: Pulmonary Rehabilitation for COPD in older patients

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Abstract

Pulmonary rehabilitation (PR) is established as an effective intervention in optimising function and quality of life in patients with COPD. However, there is limited data on the effectiveness of PR in older patients with COPD.

We reviewed all patients attending an 8 week outpatient programme. Patients were divided into two groups; Group A (n=202), below 70 years and Group B (n=122), above 70 years of age. Outcomes in both patient subgroups were compared using FEV_1, Incremental Shuttle Walk Test (ISWT), Endurance Shuttle Walk Test (ESWT), Grip Strength, St. George's Respiratory Questionnaire (SGRQ), Hospital Anxiety and Depression Score (HADS), and COPD Assessment Test (CAT) score. Statistical analysis was conducted using Mann-Whitney non-parametric testing and Chi-squared testing for comparison of clinically relevant improvements between groups.

There was no significant difference in PR outcomes between Group A and Group B using absolute values. Mean changes for ISWT in Group A and B 39.7m vs. 32.8m (p=0.63) respectively, SGRQ -2.5 vs. -2.8 (p=0.95), HADS anxiety score -0.83 vs. -0.57 (p=0.43) and HADS depression score -0.69 vs. -0.39 (p=0.48) respectively. There was no difference in the proportion of patients who achieved the minimally clinically significant improvement in Group A versus Group B in for parameters ISWT (38.6% vs 42.7%), SGRQ (27.8% vs 21.3%), HADS total score (20.5% vs 28.1%).

These data suggest that benefits of PR in COPD are not age dependent. Age should not be a barrier to enrolling patients with COPD in PR programmes.

ABBREVIATIONS: COPD=chronic obstructive pulmonary disease, PR = pulmonary rehabilitation, BMI = body mass index, FEV_1 = forced expiratory volume in one second, ISWT= incremental shuttle walk test, ESWT = endurance shuttle walk test, SGRQ = St. George's Respiratory Questionnaire, HADS = hospital anxiety and depression score, CAT = COPD assessment test, HRQoL = health related quality of life, mMRC = Modified Medical Research Council score, MCID = minimal clinically important difference, ADL = activities of daily living.

Introduction

Chronic Obstructive Pulmonary Disease (COPD) is associated with increased morbidity and mortality worldwide. It is the fourth leading cause of death worldwide and is predicted to be the third most common cause of death by 2020 [1]. In Ireland, COPD has an estimated prevalence of 400,000 people from a population of 4.58 million and according to the INHALE report [2]. The prevalence of COPD is increasing in older age groups [3]. In the context of an ageing population, it is evident that health burden of COPD and its co-morbidities will continue to increase and exert a major impact on health services internationally [2,4]. Pulmonary rehabilitation (PR) plays a crucial role in the care of COPD patients and has been shown to reduce improve exercise and functional capacity and reduce exacerbations [1,5,6,7]. Many studies have established the effectiveness of PR in improving exercise tolerance, health related quality of life (HRQoL) as well as reducing dyspnoea, exacerbations and hospitalisations [8-11]. The effectiveness of PR in older patients with COPD has been examined in a number of small studies however, it has not been convincingly demonstrated that older patients respond as well to PR as younger patients [12-15]. The aim of this study was to compare the efficacy of PR in a large cohort of COPD patients above and below the age of seventy years.

Methods

A retrospective review was performed on all patients with a confirmed diagnosis of COPD, who completed a 8 week, 16 session, outpatient PR programme over 6 years between 2008 and 2014. This was an outpatient programme based in a local community hospital with gym and educational facilities. Patients were referred to the PR programme through the outpatient service of the Department of Respiratory Medicine, Cork University Hospital by the lead physician for COPD and PR (MTH). Patients were only excluded if they could not access the facility for logistical reasons or were deemed neurologically or cardiologically unsuitable for an outpatient PR programme. Individually prescribed exercise programmes were designed for patients by an experienced COPD physiotherapist and nurse specialist. Full physiological assessments took place before and immediately after completion of the PR programme. Sixteen educational sessions were provided by the consultant respiratory physician, respiratory physiotherapist and COPD nurse specialist, social worker, professional smoking cessation counsellor and clinical psychologist.

The patients were divided into two groups; Group A below the age of 70 and Group B, above 70 years. Patient demographics and PR outcomes were collected from the programme database. Outcome measures analysed were forced expiratory volume in one second (FEV_1), Incremental Shuttle Walk Test (ISWT) distance, Endurance Shuttle Walk Test (ESWT) time, Grip Strength, St. George's Respiratory Questionnaire (SGRQ) and Hospital Anxiety and Depression Score (HADS), Modified Medical Research Council (mMRC) and CAT (COPD assessment test) scores. Data was analysed using SPSS V.21. The efficacy of PR was assessed by comparing the differences in the evaluated parameters between the two groups. Mann-Whitney U test and Chi-squared test were used to evaluate changes in parameters post-programme by age group in three ways, in keeping with

approaches used in previous studies; change in mean raw measures as illustrated in **table 2**, mean % change from baseline in **table 3** and proportion of patients achieving minimally clinical significant improvement. For some parameters the dataset was incomplete and this is reflected in the results tables below. Both Mann-Whitney U and Chi –squared testing were also used to determine whether there was a significant difference between groups defined by clinically significant change [16] in ISWT, SGRQ, HADS and CAT corrected for their baseline mean BMI, (dividing the patient cohort into those with BMI < 20 versus those ≤ 20), FEV_1 (those < 1 L/s versus those ≥ 1 L/s) and CAT score (those with CAT score < 20 versus those with a score ≥ 20). P-values of less than 0.05 were considered statistically significant throughout. This study was approved by the clinical research ethics committee (CREC) of the Cork University Hospitals.

Results

A total of 324 COPD patients attending the PR programme were analysed, of whom 122 patients were 70 years of age or above. In Group A, the mean (SD) age was 61 (3.79) years while in Group B was 75 (6.9) years. Patients' mean baseline characteristics are shown in Table 1. Table 2 shows the mean change in raw measures post PR programme by age group. Mann Whitney U testing showed that there was no significant differences in the changes achieved between the younger Group A patients and the older Group B patients. Table 3 illustrates the % change in parameters post-programme in order to take into account the differences in baseline parameters between the groups. Again, no significant differences between age groups were found.

We also compared the proportion of patients achieving clinically significant improvement in parameters between age groups using a Chi squared test. Parameters examined were ISWT – (MCID 47.5M) [17], total SGRQ score (MCID -4) [18], total HADS score (MCID 1.5) [19] and CAT score (MCID 2). There is no universally accepted MCID for grip strength.

38.6% of patients in group A and 42.7% of patients in group B achieved a MCID in ISWT distance walked post PR programme. This difference was not significant between groups. 27.8% of patients in group A and 21.3% in group B achieved MCID in SGRQ score post programme. This difference was not significant between groups. 20.5% of patients in group A and 28.1% of patients in group B achieved a MCID in HAD score post PR programme. This difference was not significant between groups. Finally, 26.5% of group A patients and 25.9% of patients in group B achieved MCID in CAT scores post PR programme and again there was no significant difference between groups. Overall taking into account all 3

parameters, 56.2% patients in Group A and 51.4% of patients in Group B achieved an MCID in at least one of the 3 parameters measured and there was no significant difference between groups.

When we attempted to control for patient cohort baseline FEV_1, CAT score and BMI to determine if these baseline parameters were associated with better outcomes from PR across the group (**table 4**) as a whole and in both the younger and older patient cohorts we found the following: The numbers with low BMI (<18.5) were very small (n=8) and thus the data was insufficient for comparison. Using both Mann U Whitney (p=0.007) and Chi squared analysis (p=0.003), a lower FEV_1 (<1 L/s) pre-programme (at baseline) was associated with a clinically significant improvement in HADS score across the whole population over the course of the PR program. Those with lower FEV_1 were found to be most likely to gain improvement in both anxiety and depression scores. This relationship was found to be age independent, baseline FEV1 <1 L/s versus HADS improvement in Group A (p=0.011) was matched by the improvement in HADS in the low FEV1 in Group B (P=0.017).

In contrast in Group A, under 70 year old COPD patients, those who achieved with a clinically significant improvement of >2 points in CAT score had a higher FEV_1 at baseline (≥1 L/s), (p=0.01). Looking at baseline CATS scores to define predictors of response we found the following: A lower baseline CAT is linked to clinically significant change in CAT across age groups. A lower baseline CAT (<20) was linked to clinically significant change in ISWT in Group B (>70 years) but not in Group A, however, a lower baseline CAT (<20) was linked to clinically significant change in SGRQ Group A but not in Group B.

Those who achieved a clinically significant improvement in ISWT had a lower CAT score (<20) at baseline in Group B (p=0.007, Mann U Whitney, p=0.014 Chi squared). In Group

A, this relationship was significant using comparison of means (p=0.01) but not by Chi squared test.

A low CAT score at baseline did not predict improvement of SGRQ scores in Group B, but did predict improvement in SQRG in the younger Group A (p=0.01 Mann U Whitney, p=0.05 Chi squared)

Discussion

The efficacy of PR is well recognised as a therapeutic intervention in COPD patients; however, the benefits amongst older patients remain unclear. Our data suggest that COPD patients over the age of 70 years benefit from a comprehensive outpatient PR programme to a similar extent to their younger counterparts under 70 years.

COPD is a growing problem in the older patients and is often undertreated. [20] Some previous PR studies, have excluded patients over the age of seventy. [21,22] It is apparent PR has sometimes been considered inappropriate for older patients because of the physiological effects of ageing which would limit their ability to take part or improve their exercise capacity. The justification for age exclusion remains ambiguous, nevertheless patients over the age of 70 years are frequently excluded along with patients with other co-morbidities such as ischaemic heart disease, heart failure or and arthritis. [22,23] Furthermore, clinical trials commonly use the age seventy as the lower limit for patient recruitment based on the consideration that those between the age of 65 and 70 years have a general health status that is good enough to benefit from therapeutic interventions that are often used in younger patients. [24] We chose a threshold of seventy years for our study to test the hypothesis that age should not be a barrier to the benefits of PR in COPD. There are data in the literature that older patients and older patients with severe COPD benefit from PR. Couser *et al* compared the effects of inpatient and outpatient pulmonary rehabilitation on old older patients COPD patients (aged 75 years or over) and younger subjects.[12] The data from this study suggest that 6-month comprehensive outpatient PR programmes are as beneficial in

older patients with severe or very severe COPD as they are in younger. The authors suggested that patients with seriously impaired lung function and major exercise limitation (n=150 patients, 17 patients over age 75 years with severe COPD) could benefit from a 6-month ambulatory multidisciplinary PR programme, although they often have significant co-morbidities. Adherence levels and benefits of older patients with COPD to this long duration comprehensive programme were in the same range as those seen younger patients.

One of the strengths of our study was the large sample size of 324 patients and the long time frame of 6 years over which the data was compiled compared to other studies conducted in similar area. Katsura demonstrated that Pulmonary rehabilitation is an effective treatment in terms of improving dyspnoea, exercise capacity and HRQoL in older COPD patients, and the benefits are almost comparable for young-older patients and old-older patients patients. However, this was a small study (n=59) and a 2 week programme. [13] Our study involves a much larger cohort over 8 weeks and with patient numbers in both groups, allowing for a high quality analysis to be carried out. Roomi *et al* assessed the effects of incremental pulmonary rehabilitation for 12 weeks on older patients COPD patients over 70 years of age. In a limited small cohort, they showed a significant increase in exercise capacity on the 6MWD. [25] Our study, which has the largest described cohort to date of older patients, showed that both patient groups demonstrate comparable improvements in functional and quality of life scores, with a majority of patients exceeding MCID thresholds in measured clinical parameters in both groups.

The main limitation in this study is that it is retrospective and we do not have extensive follow up data on long term patient outcomes and compliance with exercise post programme. We have a large patient cohort and an 8 week, 16 session programme, however the data

collection though comprehensive, was not complete. Some baseline parameters, such as the body mass index, blood pressure and other co-morbidities were not measured. These details could have made the study more informative; to assess their impact on patients' performance post PR. Interviewer bias should also be taken into consideration. Apart from that, there was no control for both groups, but it would have been unethical to refuse PR to these COPD patients who remain symptomatic.

From a functional aspect, both patient groups in this study had a negligible difference in their lung function after PR. There was a relatively equal mean improvement seen across all parameters in both groups following rehabilitation, with the exception of FEV_1. This is similar to other studies which have shown that PR does not have a discernible effect on the FEV_1 [8,10] confirming that that the benefits of PR are in improvements in patients' quality of life and functionality rather than demonstrable improvements in pulmonary physiology.

The ISWT distance increased by 25% (39.7m) in Group A and 43% (32.8) in Group B albeit from a lower baseline after PR. The older patients group did not attain an improvement that would indicate a significant clinical response. However, as ISWT reflects the domestic functional capacity of an individual, any positive change in exercise performance should be considered as beneficial to the patient. [17] The same improvement in walk distance gain can have a very different clinical meaning depending upon the baseline performance: a 70-m gain may in fact provide either a negligible or substantial effect of the functional improvement depending upon whether baseline walk distance was 250m or 100 m. Indeed, there is a strong association between the walk distance and the level of independence in basic and instrumental activities of daily living (ADLs). A comprehensive 12-week outpatient PR programme has been shown to increase both 6 minute walk distance and activities of daily

living. [26] Relatively small improvements in walk distance in older patients who naturally have a lower baseline walk distance may correspond to very clinically relevant improvements in ADLs and personal independence, even allowing for modest real improvements as in the case in our study. Similarly, a severe limitation in physical capabilities should not be a reason for excluding older patients COPD patients from a PR programme; rather these patients may achieve the greatest benefit. [15]

A strength of this study is that we recorded both ISWT and ESWT in our patient cohort. Pepin et al validated the ESWR in terms of improvements perceived by patients. A change in endurance shuttle walking performance of 45 - 85 s (or 60-115m) after bronchodilation is likely to be perceived by patients. [27] Improvements of 78s and 68s in Groups A and B respectively are almost certainly going to be perceived as beneficial in our study. Again there was no significant difference between groups and the same argument likely applies as to why there is a slightly smaller improvement in the older group who had a lower baseline. This should not detract the very significant clinically important that both groups achieved after PR with older patients performing as well as their younger counterparts. In the field of COPD research, MID values have usually been reported as fixed values, expressed in the unit of the instrument. When one takes age into account, perhaps MID estimates should be expressed as a fraction of the baseline values. [28,29]

We have no MCID for grip strength from literature. Our PR program spent considerable time with patients working on upper limb strength and flexibility. This was reflected in improvements in grip strength in both right and left hands in both group A and B. In our cohort improvement in grip strength also showed no statistically significant difference between the groups. However it is notable that the relative improvements are larger in the older group who again, not unsurprisingly, started from a lower baseline. The improvement

was slightly higher in the right hand which is most likely accounted by the fact that a higher proportion of people favour their right hand.

PR has also been shown to improve patients' HRQoL and we analysed this using the SGRQ and HADS scores. A reduction of 4 units in SGRQ is considered to be the MCID. [16,18] Reductions in SGRQ were similar between the two groups, 2.5 in Group A and 2.8 in Group B. As for the HADS total score (MCID -1.5 units), Group A attained a larger reduction of 0.8, in comparison to Group B with 0.5 reduction. [19] Nonetheless, there was no statistically significant difference between the outcomes in both groups. When the HADS domains were assessed individually, depression scores dropped more than the anxiety scores in both groups. This is consistent with earlier studies. [9,10] This may be explained by the improved functional capacity that uplifts one's spirits and changes their outlook on life. The social aspect of the programme also builds healthy interactions and motivations that may contribute to this positive outcome. It is interesting that in both groups, those with a lower baseline FEV_1 benefitted most in terms of improvement in HADS score with PR, suggesting that in fact regardless of age, those with more severe COPD may derive most benefit in mood and disease related anxiety. Similarly those with more severe disease reflected by a low programme CAT score derived the most significant improvement in CAT score with PR indicating again that regardless of age, disease severity should not be a barrier to participation in a comprehensive PR programme.

Conclusion

In summary, our study suggests that PR is beneficial in both young and older patients COPD patients, although trending slightly better in the younger cohort. Thus, age alone should not

be a limiting factor to participate in a PR programme as any improvement should be patients of all age groups should be encouraged to enrol in this programme as it does have a role in improving health outcomes.

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Conflict of interest statement

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Table 1: Baseline characteristics (mean value) of the two groups of COPD patients

	Mean pre-programme parameters (SD) by age group				
Total n=324	<70 year (n=202)		>/= 70 years (n=122)		
		n		n	Mann Whitney U Test
Age	61.5 (6.9)	202	75.5 (3.9)	122	N
BMI	28.5 (6.6)	190	27.8 (6.2)	117	NS
FEV_1 (l/s)	1.37 (0.59)	196	1.24 (0.49)	117	NS
ISWT (m)	232.3 (132)	200	151 (108)	122	p<0.001
ESWT (s)	341 (321)	194	219 (225)	119	p<0.001
SGRQ Total	51.8 (16.6)	157	52.2 (15.5)	82	NS
HADS – A	8 (4.3)	198	6.3 (3.8)	122	p<0.001
HADS – D	5.9 (3.6)	198	5.3 (3.2)	122	NS
Right Grip (kg)	25.5 (10.6)	195	22.4 (9.8)	118	P<0.05
Left Grip (kg)	23.8 (10.1)	199	20.4 (8.9)	119	P<0.01
mMRC	1.47 (1.06)	123	1.39 (0.96)	71	NS
CAT	21.8 (7.6)	133	19.8 (7.7)	82	NS

Table 2 shows the mean change in raw measures post PR programme by age group. Mann Whitney U testing showed that there was no significant differences in the changes achieved between the younger Group A patients and the older Group B patients.

	Mean change in raw parameters (SD) by age group				
	< 70 years (n=202)	n	>70 years (n=122)	n	Mann Whitney U Test
FEV_1 (l/s)	-0.003(0.2)	123	0.003 (0.24)	82	NS
ISWT (m)	39.7 (71.7)	127	32.8 (62.4)	89	NS
ESWT (s)	78.4 (353)	123	68.4 (206.5)	87	NS
SGRQ Total	-2.5 (10.1)	97	-2.8 (10.5)	61	NS
HADS – A	-0.8 (2.6)	126	-0.5 (3.4)	89	NS
HADS – D	-0.6 (2.3)	126	-0.3 (2.4)	88	NS
Right Grip (kg)	1.6 (4)	129	1.2 (4.2)	86	NS
Left Grip (kg)	1.4 (4.2)	128	1.1 (3.6)	87	NS
mMRC	-0.2 (1.1)	77	-0.02 (1.4)	52	NS
CAT	-1.8 (6.0)	83	-1.7 (6.6)	58	NS

Table 3 illustrates the % change in parameters post-programme in order to take into account the differences in baseline parameters between the groups. Again, no significant differences between age groups were found.

	Mean % change in parameters (SD) by age group				
	< 70 years (n=202)	n	>70 years (n=122)	n	Mann Whitney U Test
FEV_1	0.5 (16)	123	-0.6 (15)	82	NS
ISWT	25.4 (51.5)	127	43.6 (100)	89	NS
ESWT	49.7 (106)	123	47.2 (97.6)	87	NS
SGRQ Total	-1 (34.6)	97	-6 (23.3)	61	NS
HADS – A	-0.36 (67.9)	126	13.1 (109.	85	NS
HADS – D	0.5 (73.2)	126	9.8 (73.4)	88	NS
Right Grip	11.9 (27.1)	129	22.7 (75.2)	86	NS
Left Grip	9.7 (28.5)	128	13 (48)	87	NS
mMRC	-0 (73)	77	16.9 (110.2)	51	NS
CAT	-4.4 (38.1)	83	-4.8 (43.3)	58	NS

Table 4: The association between baseline characteristics FEV_1 (Forced Expiratory Volume in 1 sec), BMI (Basal Metabolic Index) and CAT (COPD Assessment Test)

	Group A (<70 years)	Group B (>70 years)
Baseline BMI	Numbers too small for analysis	
Baseline FEV_1	FEV_1 <1L associated with: clinically significant change in HADS FEV_1> 1L associated with clinically significant change in CAT	FEV_1 <1L associated with: clinically significant change in HADS
Baseline CAT	Lower baseline CAT associated with: clinically significant change in CAT clinically significant change in ISWT (Mann Whitney only) clinically significant change in SGRQ	Lower baseline CAT associated with: clinically significant change in CAT clinically significant change in ISWT