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Preoperative Pulmonary Rehabilitation before Lung Cancer Resection: Results from two Randomized Studies

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Abstract

Complete surgical resection is the most effective curative treatment for lung cancer. However, many patients with lung cancer also have severe COPD which increases their risk of postoperative complications and their likelihood of being considered “inoperable.” Preoperative Pulmonary Rehabilitation (PR) has been proposed as an intervention to decrease surgical morbidity but there is no established protocol and no randomized study has been published to date.

We tested two preoperative PR interventions in patients undergoing Lung Cancer resection *and* with moderate-severe COPD in a randomized single blinded design. Outcomes were length of hospital stay and postoperative complications.

The first study tested 4 weeks of guideline-based PR vs.usual care: that study proved to be very difficult to recruit as patients and providers were reluctant to delay surgery. Nine patients were randomized and no differences were found between arms.

The second study tested ten preoperative PR sessions using a customized protocol with nonstandard components (exercise prescription based on self efficacy, inspiratory muscle training, and the practice of slow breathing) (n=10) vs.usual care (N=9). The PR arm had shorter length of hospital stay by 3 days (p=0.058), fewer prolonged chest tubes (11% vs. 63%, p=0.03) and fewer days needing a chest tube (8.8vs.4.3 days p=0.04) compared to the controlled arm.

A ten-session preoperative PR intervention may improve post operative lung reexpansion evidenced by shorter chest tube times and decrease the length of hospital stay, a crude estimator of post operative morbidity and costs. Our results suggest the potential for short term preoperative Pulmonary Rehabilitation interventions in patients with moderate-severe COPD undergoing curative lung resection. 4 weeks of conventional preoperative PR seems non feasible.

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Keywords

COPD; Pulmonary Rehabilitation; Lung Cancer; Emphysema; Exercise Outcomes; Thoracic Surgery

Background

Complete surgical resection is currently the only curative treatment for lung cancer. However, many patients with lung cancer also have severe COPD which increases their risk of postoperative complications [1] and their likelihood of being considered "inoperable." No preoperative intervention to date has been proven to decrease the risk of post operative complications in patients with resectable lung cancer and poor lung function.

Pulmonary Rehabilitation (PR), an intervention that improves exercise capacity in severe COPD[6] has been proposed as an adjunctive preoperative therapy to decrease the risk of postoperative pulmonary complications[7–13] Despite experts' recommendations, no randomized study has been published to date.

The present report is the result of two *randomized single-blinded* exploratory studies (PR vs usual care) funded by the National Cancer Institute aimed to define a preoperative PR intervention that may decrease the operative morbidity of curative lung cancer resections in patients with moderate-severe COPD.

Methods

These exploratory randomized studies were conducted at University of Pittsburgh (IRB#0603002) and Mayo Clinic (IRB# 08-007135). All patients signed an informed consent.

Inclusion criteria

Patients had to have lung cancer resection by open thoracotomy (segment, lobe or pneumonectomy) or by Video Assisted Thoracoscopy (at least lobe) and moderate to severe COPD. Moderate to severe COPD was defined as $FEV_1/FVC<0.7$ and $FEV_1<61\%$ *or* $FEV_1<80\%$ having significant dyspnea defined as grade 3 or higher of the Medical Research Council Dyspnea score (MRC) A previous comprehensive report indicated an $FEV_1<61\%$ is associated with an increased risk of post operative complications [1].

The first randomized study tested 4 weeks of preoperative PR using the current guidelines for exercise prescription [17] vs usual care.

The second randomized study and tested a ten-session preoperative PR that used the following protocol:

Lower extremity (LE) endurance training had a target time of 20 minutes and was performed on a treadmill or Nu-Step (NuStep, Inc. Ann Arbor, Michigan). Upper extremity (UE) endurance was performed by arm-R-size exercises or the use of an arm ergometer or the Nu-Step.

Strengthening exercises with Thera-band (The Hygenic Corp. Akron OH) were preformed alternating UE/LE every other day. During this program, patients were asked to perform two sets of 10–12 repetitions starting with the lowest Thera-band resistance. If the patient perception was "too easy" or "requires no effort", resistance was increased. Patients were

asked to perform exercises at an intensity that they felt high self efficacy -"very confident"- they could sustain and that was at least light by Borg scale envisioning that in patients with greater self efficacy the likelihood of performing under stress (post-surgery) would increase.

Inspiratory muscle training (IMT) was performed using the Threshold Inspiratory Muscle Trainer IMT or the P-Flex valve (Philips Healthcare Andover, MA). Patients were asked to breathe through the device to attain a level of perceived exertion of "Somewhat hard" and sustain that effort as long as they were able with a goal of 15–20 minutes of daily use. Participants were coached to establish a slow, rhythmical pattern of breathing keeping inspiration and expiration times equal while using the IMT. When participants were able to complete 10 minutes of IMT time in a session or noted perceived exertion less than "somewhat hard", the next IMT setting was increased to achieve the desired effort. Incentive Spirometry training used a protocol that was reported to be associated with decreased postoperative atelectasis after thoracic surgery[18].

The Practice of slow breathing (prolonging expiratory time and thereby decreasing respiratory rate to less that 10 breaths per minute) was routinely included. Patients were instructed to "just watching their breath with pursed lips to prolong the expiratory phase" for at least 10 minutes in each PR session. During the practice of slow breathing, we promoted discussions about concerns, fears and expectations regarding surgery. We emphasized the *critical importance of the patient's role in their recovery during the post operative period* (ie. Resilience when facing pain and practicing frequent (hourly) posture, shoulder, pulmonary toilet exercises, and particularly early ambulation). Weekend exercise recommendations were given based on their prior performance in PR: individualized goals were set collaboratively. Participants were expected to engage in walking once daily, complete the IMT routine and upper extremity exercises.

Outcome measures

End points of these two studies were hospital length of stay and post operative pulmonary complications (pneumonia (new infiltrate + either fever (>38.5 C) and white cell count >11,000 or fever and purulent secretions), severe atelectasis (requiring bronchoscopy), prolonged chest tubes (>7days), and prolonged mechanical ventilation (>24hours)).

Outcomes were obtained using chart review by a nurse trained in the abstraction of the desired outcomes from the medical records and blinded to the treatment.

Data analysis

Continuous variables were tested between the two treatment arms (PR vs. control) using nonparametric Wilcoxon tests. Categorical variables were tested using Fisher's exact tests. A linear regression model was used to test for differences in length of stay between arms after adjusting for age and gender. All tests were two-sided tests using 5% type I error rates. SAS (NC) was used for the analyses.

Results

Study #1: 4 weeks of preoperative PR vs. usual care

This study had very poor recruitment, mainly due to the fact that patients or providers were not willing to delay the curative surgery for 4 weeks. Nine patients were randomized to this study in 18 months from a large surgical practice (5 hospitals: academic (three) and community (two)). Patients in each arm had similar baseline characteristics regarding age, lung function, dyspnea score (Medical Research Council Dyspnea score), history of exacerbations and comorbidities. All 5 patients randomized to PR successfully completed 4

weeks of treatment and no adverse effects were observed. This study was finally stopped due to the low likelihood of meaningful accrual during the funding period. No differences were found between the arms in any outcome.

Study #2: Ten sessions of preoperative PR vs usual care

19 patients were randomized to this study in one year from one site (Mayo Clinic). Nine patients were randomized to the control arm and 10 patients to the pulmonary rehabilitation arm. All 10 patients randomized to PR successfully completed 10 face-to-face sessions of treatment in one week (twice a day) and no adverse effects were observed. Table 1 shows patient demographics for these 19 patients. Baseline characteristics were evenly distributed between the two arms. Results of this one-year study needed to be analyzed due to the end of the funding period and report to NIH.

Two patients (one on each arm) were missing length of stay data; because they were considered inoperable once they were in the operating room and were excluded from the outcome analysis (final analyses were based on data from 17 patients). There were no differences in the frequency of open thoracotomies or pneumonectomies between the two groups we handled the analysis to not be affected by any extreme value.

Patients in the PR arm had fewer days needing a chest tube (mean days of 4.7 vs. 9.0, p=0.03) and a lower incidence of prolonged chest tubes (>7days) compared to the controlled arm (11% vs. 63%, p=0.03). Also, patients in the PR arm had on average over fewer days in the hospital compared to patients in the control arm, a difference that was very close to being significant (mean days of 6.4 vs. 11.1, p=0.058). Patients did not improve the shuttle walk test (baseline test was 31 shuttles or 310 meters) after the short term PR (p=NS).

Discussion

These exploratory studies represent the first randomized trials of preoperative PR in lung cancer resection in patients with poor lung function and may serve as a guide for future research in the field, particularly in the design of large confirmatory studies.

We believe these exploratory studies have aspects that deserve communication at this stage:

Our finding about the non feasibility of 4 weeks of preoperative PR is reflected the literature: the scarcity of publications, no one definitive, even when PR before lung resection has been proposed for more than a decade eloquently speaks about that. In 1997 a publication from Sloan Kettering Cancer reported an ongoing study of 3 weeks of preoperative PR that never translated in a full manuscript. After that only a few small non controlled studies (from large centers) suggested the benefit[11–13,19,20]. Our experience reflects that patients (and many times providers) facing a potentially curative resection want the cancer out NOW. While doing preoperative PR is appropriate and recommended by experts [987,19], the lack of evidence using the current methods suggest the need of new protocols adjusted to the perioperative setting.

The development of a short and *feasible preoperative PR protocol* was the natural consequence of the failure of the longer one. Our 10-session protocol showed a high likelihood of decreasing hospital length of stay, a very meaningful outcome that is crude estimation of post operative morbidity and costs. We believe we observed a true and meaningful difference in length of stay favoring the PR group (Figure 1) that barely missed the classic and rigid standards of significance (our p value for the difference of length of stay was 0.058). It is important to clarify again that we handled the analysis to not be affected by any extreme value and that both groups were balanced in procedures

(pneumonectomies, thoracotomies, VATS). We found a significant and meaningful decrease in the time of chest tube drainage and less prolonged chest tubes, a well defined pulmonary complication of lung resection in severe COPD. Our results in all outcomes favored the PR group (table two), something that reassured this group on the possible effectiveness of the short intervention, but did not attain statistical significance due to our sample size.

The goal when designing the second exploratory study was to test a feasible intervention: the one that patients and provider would agree, including evidence based components not routinely recommended in PR. Those components were: self efficacy-based exercise prescription, the routine use of inspiratory muscle training (IMT), and a dedicated practice of slow breathing (considered “the relaxation part” by patients).

We believe that by targeting self efficacy more than intensity as the primary focus of all exercise training we introduced an innovative behavioral aspect in this short PR intervention. We envisioned that patients that felt very confident in performing certain key activities (ambulation, upper extremity mobility, stretching), they would have a higher likelihood of doing them in the postoperative setting: and we communicated that exact message to the patients. To achieve this goal of greater self efficacy, we empowered patients to do what they were really confident to do, intending to foster their autonomy in their rehabilitation process and preparation for surgery. Self efficacy has been identified as an important mediator for behavioral changes in patients with COPD [21] and cancer [22–24], and very recent reports emphasized the importance of promoting self efficacy in PR[25,26]. The self efficacy theory [27,28] is the foundation of many disease self management programs [29–31]. We speculate that greater self efficacy (for dealing with symptoms and for starting early post operative ambulation even in the context of pain and dyspnea) mediated, at least in part, the benefits observed. We could not attribute the benefits of the intervention to increased exercise capacity - as there was a lack of change in the shuttle walk test pre/post rehabilitation-.

Our finding of shorter time of chest tubes in place may indicate a better lung reexpansion, a result that may be associated with the routine use of preoperative Inspiratory Muscle Training (IMT). The positive impact of preoperative physiotherapy involving IMT on lung reexpansion is not a new discovery: in a recent study that included 263 patients undergoing thoracic surgery, patients received 1 day of preoperative PR (incentive spirometry, deep breathing exercises, coughing and promotion of early ambulation) and the incidence of postoperative atelectasis was significantly decreased by 50% [18]. The impact of preoperative IMT on the outcomes of thoracic surgery has been addressed by a randomized study published in JAMA by Hulzebos et al that randomized of 279 patients to *2 weeks* of preoperative IMT vs. usual care that reported a reduction of post operative complications in patient undergoing thoracotomy. The latter being the strongest evidence to date for the use of IMT in the preoperative setting[32]. In Moreover, another recent randomized study showed that inspiratory muscle strength was a determinant of functional capacity after thoracic surgery[33].

The practice slow breathing (decreasing the respiratory rate by prolonging the expiratory phase), has been one of the initial strategies of PR (while practicing pursed-lips breathing) and is still an open area for therapeutic target in COPD as recently suggested by Macklem[34]. Slow breathing has been shown beneficial in COPD by decreasing sympathetic tone [35], in thoracic surgery improving postoperative pain management [36] and invariable brought a sense of relaxation in our group, a factor associated also with improved post operative outcomes [37] (and for that reason we strongly recommended in the post operative period).

Why a 2-week intervention?

Three studies reported improved postoperative outcomes with short interventions: the study by Hulzebos et al (2 weeks of IMT) mentioned before[32], a study by Sekine et al reported that 2 weeks of preoperative PR decreased length of hospital stay [20] and a study reported that 1 day of preoperative physiotherapy significantly decreased post operative atelectasis[18].

Our results require confirmation by a larger and likely multicenter study. Even in awareness of the preliminary nature of our results, we believe our findings have practical implications: a short feasible preoperative PR protocol may have potential to improve surgical and may easily translate to practice. In addition, our work may serve for a start in filling the knowledge gap on effective preoperative care including aspects that are not routinely used: IMT, the practice of slow breathing and self efficacy based exercise prescription, all aspect of PR that can make a difference in outcomes. The use of preoperative PR is a challenge in rehabilitation science (duration and components) and our results may represent a possible answer.

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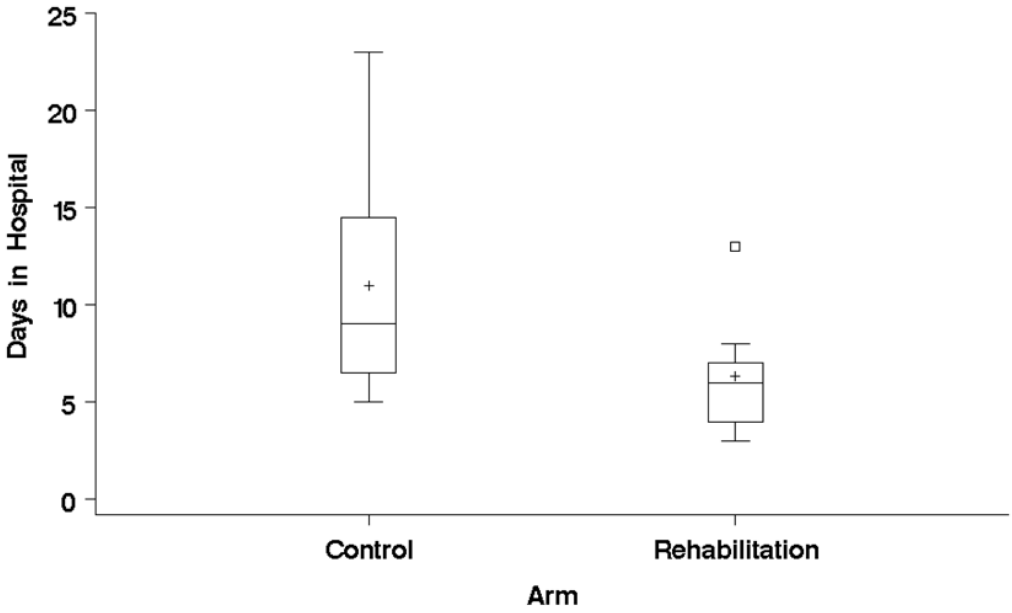

Figure 1.
Box plot of Days in the Hospital by Treatment Arm

TABLE 1

Baseline characteristics before ten sessions of Pulmonary Rehabilitation

	Control (N=9)	Pulmonary Rehabilitation (N=10)	p value
Age, mean (SD)	72.0 (6.69)	70.2 (8.61)	0.71
Female, n (%)	5 (56%)	5 (50%)	0.81
Current Smoker, n (%)	2 (22%)	1 (10%)	0.47
Cigarettes Per Day, mean (SD)	26 (7.2)	24 (14.3)	0.37
Years Smoked Cigarettes, mean (SD)	46 (6.4)	43 (10.4)	0.62
Coronary Artery Disease (%) history	1 (11%)	3 (30%)	0.31
Heart Failure, n (%) history	0 (0%)	0 (0%)	--
Diabetes, n (%)	3 (33%)	3 (30%)	0.88
MRC Dyspnea Score	2.0 (0.82)	2.3 (1.49)	0.43
FEV1 % Predicted	52.1 (13.32)	43.4 (10.18)	0.11
DLCO % predicted	60.3 (18.32)	48.9 (10.79)	0.24
Residual Volume % predicted	160.4 (31.11)	186.4 (57.97)	0.60

TABLE 2

Postoperative Outcomes after ten sessions of Pulmonary Rehabilitation

STUDY #2	Control (N=8)	Pulmonary Rehabilitation (N=9)	p value
Days in Hospital, mean (SD)	11.0 (6.3)	6.3 (3.0)	0.058
ICU Hours, mean (SD)	40.5 (75.2)	14.9 (44.7)	0.39
Number of patient that had Post-Op Pulmonary Complications, n (%)	5 (63%)	3 (33%)	0.23
Ventilation Hours, mean (SD)	33.3 (61.9)	6.0 (18.0)	0.39
Number of patient that had prolonged Chest Tube (>7days), n (%)	5 (63%)	1 (11%)	0.03
Average number of days with Chest Tubes, mean (SD)	8.8 (5.3)	4.3 (2.1)	0.04
Respiratory Failure, n (%)	2 (25%)	1 (11%)	0.45
Pneumonia, n (%)	2 (25%)	1 (11%)	0.45
Number of patients requiring bronchoscopy for atelectasis (%)	2 (25%)	1 (11%)	0.45