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Impact of a Pharmacist-led COPD Clinic on Patient Outcomes in a Rural Healthcare Clinic

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Abstract

Background

While it is well documented that pharmacists improve disease state outcomes, there are currently no studies evaluating a pharmacist's impact on quality of life (QOL), lung function, and adherence in COPD patients, specifically in a rural healthcare setting. We aimed to compare changes in patient QOL with and without participation in a pharmacist-led COPD clinic in a rural healthcare setting.

Methods

This was a single-center, prospective, open-label, case/control study performed at a rural healthcare center during December 2018 through June 2019. Enrolled patients were assigned to either the case or control arm on an alternating basis. Case participants received individualized patient care including PFT, QOL assessment utilizing the St. George's Respiratory Questionnaire (SGRQ), disease state education, and medication management for a total of 3 appointments during a 6-month period. Control subjects did not receive the individualized intervention during the 3 appointments and only completed the PFT, SGRQ, and medication adherence counseling.

Results

A total of 20 patients participated in the complete 6-month COPD clinic. At the end of the 6-month clinic, there was not a statistically significant difference between the groups in regard to SGRQ values (p=0.191), medication adherence (p=0.279), and lung function (p=0.321). Limitations included randomization methods and sample size.

Conclusions

Although there was not a statistically significant difference between the groups; significant mediation management interventions were made for participants in both the intervention and control groups. Pharmacists are well positioned in multiple practice settings to contribute to the improvement of quality of life for these patients.

Background

Chronic obstructive pulmonary disease (COPD) is the fourth leading cause of death in the world.[1] In the US, there are 16 million people living with COPD and associated healthcare costs are near 32 billion dollars annually.[2] In North Carolina, 48.7% of patients with COPD visited a provider for symptoms in the previous year and 17.6% reported a hospital admission or emergency department visit for COPD.[3]

Xin and colleagues studied the impact of a pharmacist-managed COPD clinic.[4] This 12-month study demonstrated improved medication adherence and quality of life through individualized education on COPD and associated medications.[4] A meta-analysis by Zhong et al. reviewed pharmacist involvement in COPD patient care.[5] Of the eight trials included in the analysis, four studies demonstrated a significant improvement in quality of life. The meta-analysis concluded that pharmacist involvement in COPD management was associated with improved adherence, decreased hospital readmission rates and health-related costs.[5]

It is unknown whether pharmacist involvement improves the management of COPD in the rural healthcare setting. Rural healthcare clinics provide care to patients who otherwise would not receive it due to limited resources.

The study took place at a community-owned non-profit rural health care center that serves insured and non-insured patients through a payment assistance program. The healthcare center has approximately 700 patients diagnosed with COPD per ICD-10 codes. The clinic utilizes spirometry and Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines to manage patients with COPD.

Objective

To compare changes in patient quality of life (QoL) before and after enrollment in a pharmacist-led COPD clinic. Other objectives included a comparison of forced expiratory volume in one second (FEV1) values as well as patient adherence to maintenance COPD medications before and after enrollment into this clinic.

Methods

This was a single-center, prospective, open-label, case/control study. Patients were screened between October 2018 and December 2018 and were self- or provider-referred. Patients were included if: ≥ 40 years, established diagnosis of COPD ≥ 6 months, fluent in English, and able to perform pulmonary function testing (PFT) at least twice during their care. Patients were excluded if: data was missing for analysis or had a concomitant diagnosis of asthma, active lung cancer, pulmonary fibrosis, or pulmonary hypertension. Enrolled patients were placed in the case or control group on an alternating basis Control participants were matched for analysis to intervention participants based upon age group (i.e. 50s, 60s, 70s, etc.) and did not receive the individualized disease state education (Figure 1).

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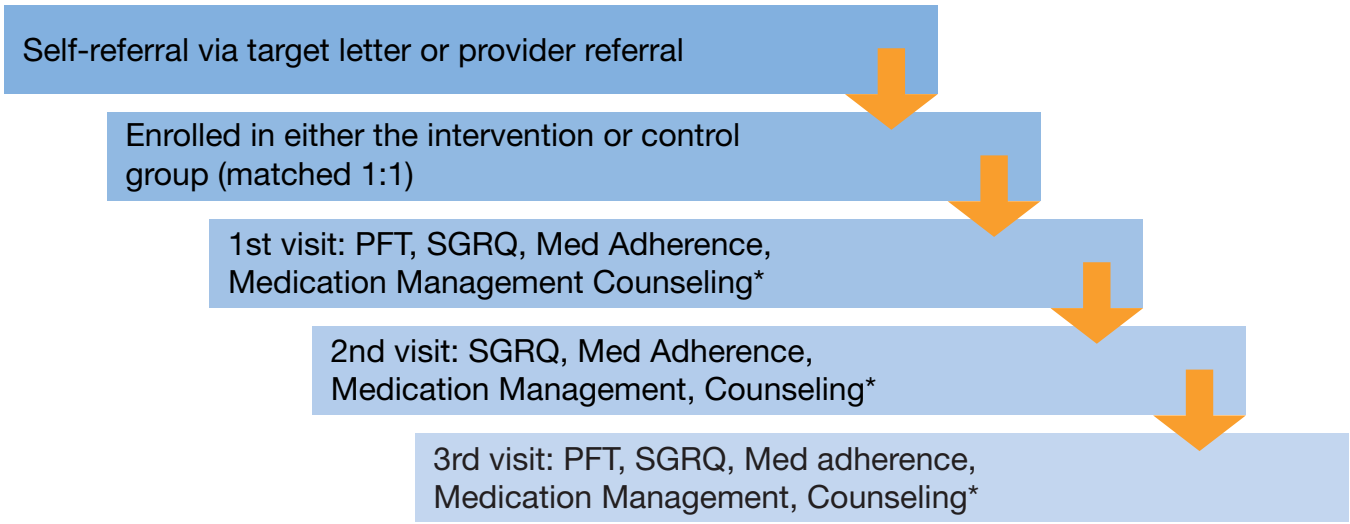
Figure 1



* indicates that counseling was only completed for the intervention group

Figure 2

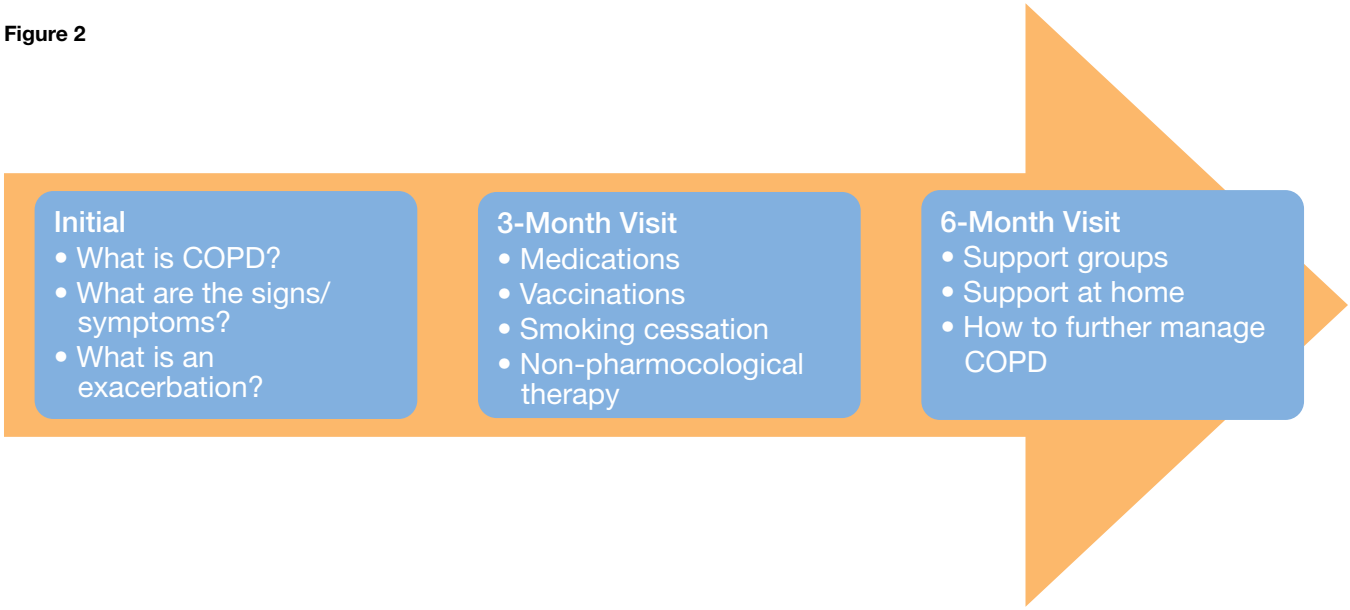
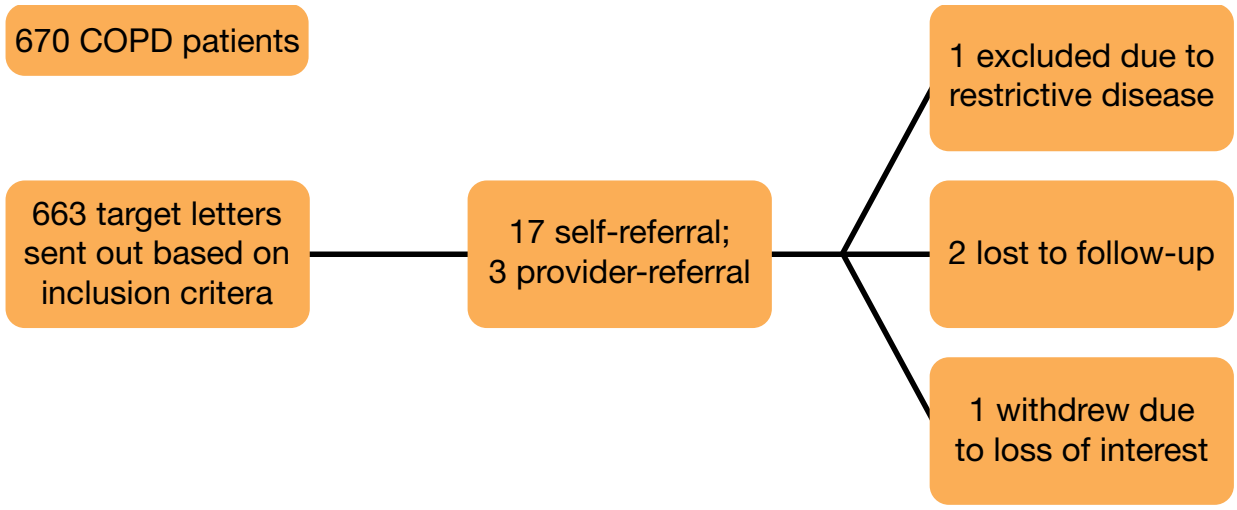


Figure 3



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Patients were evaluated during three separate encounters between December 2018 and June 2019. The pharmacist-led COPD clinic involved medication education with inhaler device teaching at each visit. The pharmacist performed PFTs, QoL assessment utilizing the St. George's Respiratory Questionnaire (SGRQ) and provided disease state education (Figure 2).

The primary endpoint was change in SGRQ value. Secondary endpoints were change in FEV1 and adherence of maintenance COPD medications. The SGRQ total score (0 to 100) summarizes the impact of the disease on QoL where a change of four points in the SGRQ score is associated with slightly effective treatment, 8 points with moderately effective treatment, and 12 points with highly effective treatment.[7] Adherence was calculated for maintenance medications only and determined based on Table 1 prior to each visit.

Table 1. Medication Adherence Scoring based on Fill History

Pharmacy Fills in Past 3 Month Period	*Score*
Missed no refills	0
Missed one refill	1
Missed two refills	2
Missed three refills	3

Based on our preliminary analysis, our goal was to enroll 165 patients and retain 150 patients to provide an 86% power of detecting a clinically significant difference based upon an alpha of 0.05. The endpoints were analyzed using the Wilcoxon-Signed Rank test (JMP 14.0.0, SAS Institute, Cary, NC).

Results

A total of 633 patients were identified for possible inclusion and, of these, 20 patients were enrolled. One patient was excluded due to restrictive disease, two patients were lost-to-follow-up and one patient withdrew from the study, leaving 16 evaluable patients.

Baseline characteristics (Table 2) were similar among the groups. Most patients were elderly, Caucasian, and had similar inhaler use. Control patients had a slightly higher FEV1 at baseline and were mostly males. Intervention patients were more commonly female.

Three-month data point

The mean change in SGRQ value for the intervention and control groups were -13.9 and -4.35, respectively and was not significantly different (p = 0.195). The mean change in participant adherence was -0.29 and 0.6, respectively, with no significant difference (p = 0.353) (Table 3).

Medication interventions totaled seven in the control group and five in the intervention group. Interventions included initiation of a short-acting beta agonist (SABA), a long-acting muscarinic antagonist (LAMA), a combination LAMA and long-acting beta agonist (LABA), and triple therapy including a LAMA, LABA, and inhaled corticosteroid (ICS). Smoking cessation counseling was provided to three patients and no vaccinations were given due to participants having up-to-date vaccination records.

Table 2. Baseline Characteristics

	Control (N=8)	*Intervention (N=8)*
Mean age (years)	73.4	73.2
Male (%)	62.5	40
Race-Caucasian (%)	100	100
Baseline FEV1 (% predicted)	72	63.2
Baseline Inhaler Use (n)		
SABA Only	3	3
LABA + ICS	3	2
ICS	1	-
LABA + ICS/LAMA	1	1
LAMA	-	1
LABA + LAMA	-	1

Six-month data point

The mean change from three months to six months in SGRQ value for the intervention and control groups were 1.96 and 5.63 (p = 0.568), respectively; whereas the mean change from baseline to six months in the SGRQ value were 1.97 and -10.9 (p = 0.191), respectively, neither of which was found to be statistically significant. The mean change in participant adherence from three to six months was -0.17 for both groups with no significant difference (p = 0.355). The mean change in participant adherence from baseline to six months was 0 and -0.33, respectively, with no significant difference (p = 0.279).

FEV1 was evaluated at the baseline visit and six-month visit. The mean change from baseline to six months in FEV1 for the intervention and control groups were -3.2% and 2.5%, respectively, with no significant difference (p = 0.321). The intervention group had an improvement in lung function whereas the control group did not.

Further medication management interventions made in the final appointment included initiation of triple therapy (LAMA + LABA + ICS) and a combination therapy (LAMA + LABA).. For two participants with frequent exacerbations, COPD action plans were provided along with prescriptions for a steroid and antibiotic. Smoking cessation counseling was reiterated to three participants with two of the three participants agreeing to participate with the NC Quit Line.

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Table 3. Three Month Results

	Control		*Intervention*		
	Baseline	*3 Month*	*Baseline*	*3 Month*	*P-Value*
Mean SGRQ Value	62.3	48.4			0.055
Mean SGRQ Value			37.7	26.7	0.742
Mean SGRQ Difference		-13.9		-4.35	0.195
Mean Adherence Difference		-0.29		0.6	0.353
Number of Interventions		7		5	

Discussion

The pharmacist-led clinic group was not associated with a significant difference in quality of life measures compared to the control group. COPD symptoms and their impact on daily activities are typically assessed with the modified Medical Research Council (mMRC) and the COPD Assessment Test (CAT) due to their ease of use. In our trial, however, we utilized the SGRQ to evaluate symptom control and quality of life as this was the validated questionnaire utilized by similar COPD studies previously reported. At the three-month follow-up visit, the change in SGRQ scores for the intervention group indicated a slightly effective treatment. Surprisingly, at the 3-month follow up for the control group, changes in SGRQ scores indicated a highly effective treatment. This could have been due to the control group having a poorer quality of life score at baseline compared to the intervention group. At the 6-month follow up visit, the change in SGRQ scores for the intervention group and the control group indicated that treatment was not effective; however, participants felt their treatment was adequate.

COPD symptoms are worsened by colder temperatures during winter and spring months.[8] Our study was initiated in December and concluded in June, spanning both winter and spring. The short duration of our study could also be a reason no difference was found between the groups.

Strengths

With each patient, pharmacists worked in collaboration with physicians at the rural healthcare clinic to ensure optimal patient care. A validated questionnaire for quality of life (SGRQ) that was also utilized in other respiratory studies was utilized.

Limitations

Our sample size was smaller than expected resulting in an underpowered study. Utilization of a single study site in a rural community was a contributing factor.

Our study utilized a non-validated process to assess patient adherence; therefore, adherence may not have been accurately measured. A validated approach, such as the Morisky Medication Adherence Scale would have proved beneficial to assessment of adherence, however the clinic would have had to be a part of a health system and receive special permission from the developers.

Our approach to patient recruitment and enrollment could have limited the success of our results and contributed to sample bias. Despite outreach to patients with a COPD diagnosis and physician education about our study, we had a very low response rate.. Additionally, patients were placed into groups in an alternating fashion potentially causing selection bias. A better approach would have been to utilize stratified randomization in order to account for variables such as age or gender.

Conclusion

There was no statistically significant difference between the groups for QoL, medication adherence, or lung function. Significant medication management interventions were made for participants in both the intervention and control groups. Despite the small sample size, the study provided a unique design for pharmacist interventions in patients with COPD. Pharmacists are well positioned in multiple practice settings to contribute to the improvement of quality of life for these patients. A study including a larger sample with a longer duration would be warranted to better describe the impact of a pharmacist-led COPD on patient outcomes in a rural setting.

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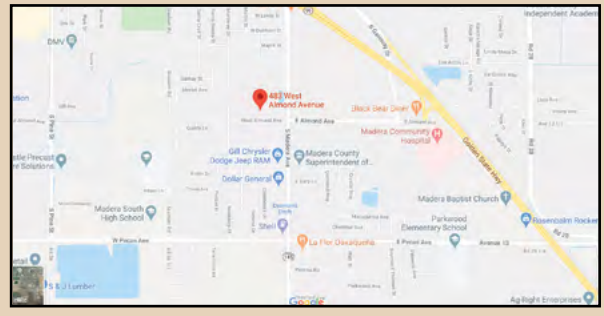

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