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

Sarah E. Russell, PharmD, BCACP, CPP; Steven W. Johnson, PharmD, BCPS, CPP, AAHIVP; Elizabeth Mills, PharmD, BCACP, CPP, CDCES

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. In the US, there are 16 million people living with COPD and associated healthcare costs are near 32 billion dollars annually. 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. Xin and colleagues studied the impact of a pharmacist-managed COPD clinic. This 12-month study demonstrated improved medication adherence and quality of life through individualized education on COPD and associated medications. A meta-analysis by Zhong et al. reviewed pharmacist involvement in COPD patient care. 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.

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 assistance to intervention participants based upon age group (i.e. 50s, 60s, 70s, etc.) and did not receive the individualized disease state education (Figure 1).
670 COPD patients

663 target letters sent out based on inclusion criteria

17 self-referral; 3 provider-referral

1 excluded due to restrictive disease
2 lost to follow-up
1 withdrew due to loss of interest

Initial
• What is COPD?
• What are the signs/symptoms?
• What is an exacerbation?

3-Month Visit
• Medications
• Vaccinations
• Smoking cessation
• Non-pharmocological therapy

6-Month Visit
• Support groups
• Support at home
• How to further manage COPD

Self-referral via target letter or provider referral

Enrolled in either the intervention or control group (matched 1:1)

1st visit: PFT, SGRQ, Med Adherence, Medication Management Counseling*

2nd visit: SGRQ, Med Adherence, Medication Management, Counseling*

3rd visit: PFT, SGRQ, Med adherence, Medication Management, Counseling*

* indicates that counseling was only completed for the intervention group
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. 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.

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.

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                  |
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. 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.

Table 3. Three Month Results

|                           | Control Baseline | Intervention Baseline | 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                     |         |

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.

Acknowledgements
The authors thank Abby Case, PharmD, for assistance with data collection throughout the project. The authors also acknowledge Richard Drew, PharmD, MS, BCPS, FCCP, and the Campbell University College of Pharmacy & Health Sciences Pharmacy Practice Research Committee for their evaluation of the research.
About the Authors
Sarah Russell, PharmD, BCACP, CPP, is a Clinical Pharmacist Practitioner and residency preceptor at UNC REX Healthcare. Dr. Russell has three years of experience in ambulatory care including a PGY1 Community-Based pharmacy residency and a PGY2 Ambulatory Care pharmacy residency. Dr. Russell has no conflicts of interest to report.

Steven W. Johnson, PharmD, CPP, AAHIVP, is an Associate Professor of Pharmacy Practice at Campbell University College of Pharmacy & Health Sciences. Dr Johnson serves on the college’s and department’s research committees. He also maintains an active practice at Novant Health Forsyth Medical Center. Dr. Johnson reports no conflicts of interest.

Beth Mills, PharmD, CPP, BCACP, CDCES, is a Clinical Assistant Professor of Pharmacy Practice at Campbell University College of Pharmacy & Health Sciences. Dr. Mills has practiced as a Clinical Pharmacist Practitioner in a primary care clinic for seven years where she manages chronic disease states including respiratory illness. Dr. Mills reports no conflicts of interest.

References
1. May SM, Li JTC. Burden of chronic obstructive pulmonary disease: Healthcare costs and beyond. Allergy Asthma Proc. 2015; 36(1):4-10. doi: 10.2500/aap.2015.36.3812.

2. COPD National Action Plan: At-A-Glance [Internet]. US Department of Health and Human Services: National Heart, Lung, and Blood Institute; 2017. Available from: https://www.nhlbi.nih.gov/sites/default/files/media/docs/COPD%20National%20Action%20Plan_At-A-Glance%20Brochure%2020508.pdf.

3. COPD among Adults in North Carolina [Internet]. Centers for Disease Control; 2012. Available from: https://www.cdc.gov/copd/maps/docs/pdf/NC_COPDFactSheet.pdf.

4. Xin C, Xia Z, Jiang C, Lin M, Li G. The impact of a pharmacist-managed clinic on medication adherence and health related quality of life in patients with COPD: a randomized controlled study. Patient Prefer Adherence. 2016; 10:1197-1203. doi: 10.2147/PPA.S110167.

5. Zhong H, Ni XJ, Cui M, Liu XY. Evaluation of pharmacist care for patients with chronic obstructive pulmonary disease: a systematic review and meta-analysis. Int J Clin Pharm 2014; 36:1230-1240. doi: 10.1007/s11096-014-0024-9.

6. Healthcare Access in Rural Communities [Internet]. Rural Health Information Hub: US Department of Health and Human Services; 2017. Available from: https://www.ruralhealthinfo.org/topics/healthcare-access.

7. Jones PW. Interpreting thresholds for a clinically significant change in health status in asthma and COPD. Eur Respir J. 2002 Mar; 19(3):398-404. doi: 10.1183/09031936.02.00063702.

8. Donaldson GC, Wedzicha JA. The causes and consequences of seasonal variation in COPD exacerbations. Int J Chron Obstruct Pulmon Dis. Oct 2014;9:1101-1110. doi: 10.2147/COPD.S54475.x.

PHARMACY SPACE FOR LEASE
IN THE CENTRAL VALLEY
483 E. Almond Ave, Madera CA 93637

• 2,500 Square Feet
• ¼ mi to Madera Community Hospital
• Abundant Parking
• Easy Access to HWYs 99 & 145
• Pharmacy Trade Fixtures Available
• Gross Lease, Terms Negotiable

The subject space was previously operated as a pharmacy for several years. It is located on a commercial corridor where the majority of Madera’s medical and dental facilities are located.

Presented by Chris DaSilva
Century 21 MM
559-232-0096
cdasilva@c21mm.com
DRE: 01926322

Downloaded from http://meridian.allenpress.com/jcphp/article-pdf/67/3/18/2622381/i2573-2765-67-3-18.pdf by guest on 23 October 2020
Children’s Nutrition that Tastes Good

ChildLife® Clinicals is a full line of liquid supplements that combine herbal ingredients and vitamins to support early-life health for infants and children.

Pediatrician Developed  Tested for Purity  Natural Ingredients  Gluten Free  Trusted by Parents

To view the full line of children vitamins visit childlifeclinicals.com

Available for healthcare providers only at emerson ecologics

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.