



Final Summary

The REVOLUTION Registry enrolled a total of 23 patients from 9 different sites starting in November 2016. Of these 23 patients, 11 patients completed a 3-month follow-up form. Procedures for biospecimen collection and handling were just being initiated as the study closed. Thus, bio-specimens were collected for only one patient and were disposed of on-site upon study termination in April 2017. The goal of this study was to characterize current real-world management of these patients and their associated outcomes. The registry aimed to evaluate patients who underwent molecular testing, what treatments patients were receiving and in which sequence, and outcomes, toxicities, and costs of these treatments from the payer, provider, and patient perspective.

Both clinical and patient reported data were collected via a web-based data collection tool. Initial patient evaluation included Disease status, Patient status, Patient Reported Outcome questionnaires, Comprehensive metabolic panel and CBC, diagnostic evaluation, and Initial local treatment. Follow-up data to be collected every 3 months included Patient Reported Outcome questionnaires, disease status, change in treatment and healthcare overall and Status of systemic treatment.

The study population was composed of 65% males (15/23) with a median age of 64 (IQR 58-74). One patient was self-reported Hispanic (4%) and 17% (4/23) were black. There was an even distribution of insurance payers with patient coverage (some double coverage) that included 35% Medicare, 35% private, 13% military, and 22% non-Medicaid state-specific plans.

Frequently encountered comorbid medical conditions included hypertension (57%), COPD (50%), dyslipidemia (39%), pneumonia (39%), emphysema (30%), diabetes (30%), arrhythmias (26%). Less frequent, but present conditions included peripheral neuropathy (13%), congestive heart failure, seizure, asthma, pulmonary fibrosis (9%). Infrequent comorbidities ($\leq 4\%$) included myocardial infarction and cerebrovascular disease.

Commonly used medications at the time of diagnosis included analgesics (70%), anti-emetics (44%), anti-hypertensives (61%), and steroids (35%). Anticoagulants were taken by 17% of patients.

Most patients had newly diagnosed disease (86%) and the remainder of reporting patients had recurrent disease (14%).

Roughly half of patients had molecular testing performed (57%). These samples were collected most commonly from lung (8/13) with other sites including blood (1), brain (1), and lymph nodes (2). PD-L1 IHC was performed in 57% of patients.

Roughly half of patients had large or advanced primary tumors, including 39% T3 and 9% T4 tumors.

At baseline, 22 patients completed some portion of the patient reported instruments. Baseline PRO information was missing for about half of the patients for each questions. Of those patients reporting marital status, half (5) reported being married with another 5 reporting being either single, divorced or widowed. For those patients who reported their employment status up to diagnosis, 54% reported being currently employed. In terms of education status, 45% of patients



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who answered this question reported having attended college. For the 11 patients reporting income, 5 (45%) reported making between \$30,000 and \$50,000/year. When asked how many miles they traveled to see their physician, 5 reported traveling between 6-10 miles, 2 patients traveled between 11-20 miles, and 3 patients traveled greater than 20 miles.

We received 3 month follow-up information for a total of 11 patients. At the time of their 3-month follow-up visit, 3 patients had died and one patient had withdrawn from the study. Seven of the patients (63.3%) for which we received 3 month follow-up information were still alive at the time of study termination and were anticipated to contribute future follow-up information.

For the patients completing 3-month follow-up visits, some PRO information was obtained for 8 (27%) of patients. Two patients reported their employment status having changed since their diagnosis.

Given the early termination and small final sample size (N=22), this report is unable to provide any statistically meaningful analysis. However, even with these small sample sizes, this report demonstrates the quality and nature of the data that was collected and gives an idea of what the larger cohort would have provided.

Some points of interest are worth comment. The patient demographics reflected an expected male predominance of patients with the vast majority having a substantial smoking history. Although not necessarily surprising, it was interesting to note that half of the study population had a diagnosis of COPD, and nearly as many had a diagnosis of pneumonia. Diabetes was present in 30% of patients, which although is not necessarily surprising, is of note. The incidence of arrhythmias at 26% was surprisingly high. The frequency of these comorbid conditions should be considered compared to that of randomized trial populations.

Most patients were ECOG 0-1 and past or current smokers. Although most, 86% of patients, presented with newly diagnosed disease, it is interesting to note that recurrent disease was also represented. Molecular testing appears common in this cohort of patients, with the majority undergoing testing. Although most patients had testing performed on a lung tumor, a third of those tested were tested at sites of metastases. No meaningful analysis of specific mutations found was feasible given the small sample sizes, but a table listing the findings is included in the appendix.

Review of patient reported outcomes was interesting in that it revealed that approximately half of patients had essentially no or minimal difficulty at all across many categories of activities. Larger sample collection might be informative as to whether these dichotomous patient populations also differed with respect to their oncologic outcomes and treatment patterns.

Measures of financial burden showed an evenly distributed range of patient reported levels of stress and concern over their finances in relation to their treatment. This suggests that the relevance of financial concerns during treatment is likely highly variable between patients and that identification of patients for which such concerns exist might help direct additional assistance. Of related interest is that there was a relatively even mix of insurance sources for patients between Medicare, private insurance, and non-Medicaid plans. Copays for doctor visits



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and other services ranged widely between patients and likely also were relevant, although few patients either knew or reported their specific copay amounts.

In summary, the REVOLUTION cohort appears to have been well-designed to collect a patient population with a mix of insurance, health, patient health status, and patient financial concerns in patients considering initiation of systemic therapy. Many of the data reported are not routinely collected within randomized clinical trials or even during routine patient care, but might be expected to significantly impact patient well-being and outcomes. Hopefully, lessons learned from this registry can form the basis for future studies to better understand how patient physical and social factors might impact treatment decisions and outcome in real world oncologic care of patients with lung cancer in the United States.