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Utilization of genomic testing in advanced non-small cell lung cancer among oncologists in the Veterans Health Administration

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ABSTRACT

Current national guidelines recommend genomic testing on all stage 4 non-small cell lung cancers (NSCLC) of adenocarcinoma histology. Mutations are most often found among young, Asian, females without a history of smoking. As these characteristics are uncommon in the Veterans Health Administration (VHA) patient population, we sought to understand oncologists' decision-making processes regarding utilization of genomic testing in the VHA. We conducted in-depth qualitative interviews with 30 VHA-based medical oncologists. Interviews aimed to elicit oncologists' experiences and decision-making processes regarding genomic testing in patients with stage 4 non-small cell lung cancer with adenocarcinoma histology. Analysis was guided by principles of framework analysis. Sample size was determined by thematic saturation. We identified a wide variation in medical oncologists' genomic testing practices. Consistent with guidelines, advanced stage and adenocarcinoma histology most often influenced practice patterns among our participants. However, patient characteristics like gender, age, smoking status, and performance status were also taken in to account by some oncologists when making testing decisions. This does not reflect a widespread adoption of national guidelines for genomic testing in the VHA. Qualitative interviews with VHA-based oncologists demonstrated that genomic testing decisions are not always consistent with current national guidelines. Efforts should be made to address modifiable barriers to genomic testing in the VHA setting.

1. Introduction

Lung cancer is the second most common cancer, and the leading cause of cancer-related mortality in the United States. An estimated 224,390 new lung cancer cases were diagnosed in 2016, resulting in approximately 158,080 fatalities in the same year [1]. The most prevalent type of lung cancer, non-small cell lung cancer (NSCLC), comprises approximately 85% of lung cancer cases [2]. The United States Preventive Services Task Force recommends annual lung cancer screening using low-dose computed tomography (LDCT) in individuals aged 55–80 years who have a history of smoking [3]. Because available diagnostic tests are expensive and invasive, the disease is difficult to detect at an early stage, which means most patients are diagnosed at advanced stages (stage IIIB or IV) [4].

Traditional approaches to lung cancer therapy include surgery, radiation, chemotherapy, angiogenesis inhibitors, and immunotherapy. Systemic chemotherapy is the conventional treatment for patients with advanced NSCLC, but more recently, genomic-based therapies have emerged, including erlotinib, crizotinib, and next generation small-molecule ROS1 inhibitors. Erlotinib, the tyrosine kinase inhibitor of the epidermal growth factor receptor (EGFR), is one such genomic-based therapy currently recommended in the National Comprehensive Cancer Network (NCCN) guidelines for first-line treatment of patients harboring the EGFR mutation. In August 2011, the Food and Drug Administration (FDA) approved another class of genomic-based targeted therapy (crizotinib) for the treatment of patients with locally

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advanced or metastatic NSCLC that tests positive for the anaplastic lymphoma kinase (ALK) mutation. Crizotinib has since been recommended in the NCCN clinical practice guidelines to treat ALK-positive cases of advanced lung cancer. Genomic-based therapies are available as treatment options in the Veteran's Health Administration (VHA).

Guidelines from the International Association for the Study of Lung Cancer (IASLC), NCCN, and the European Society for Medical Oncology (ESMO) recommend that all patients diagnosed with advanced non-squamous NSCLC undergo genomic testing, and that the results be used to guide treatment decisions [5–7]. Recent research has documented underuse of genomic testing. One 2017 study identified under-utilization of EGRF testing among Medicare beneficiaries [8]. Another recent study of 15 community-based oncology centers found significant underuse of genomic testing in patients with advanced NSCLC [9]. In this study, only 59% of eligible patients received the recommended testing for both EGFR and ALK biomarkers. Of those who received testing for both biomarkers, 13% had EGFR mutations and 3% had ALK mutations.

Mutations in EGFR tyrosine kinase are most often found among young, Asian, females without a history of smoking, characteristics not often found in the VHA [10]. EGFR mutations have been found in approximately 5–15% of NSCLC in U.S. Caucasians, most commonly in nonsmokers. The prevalence is up to 60–70% in never-smoking Asian populations with adenocarcinoma [11–13]. ALK mutations are most often identified in younger patients with no smoking history or former light smokers [14].

Given the underuse of testing that has been documented in community-based studies, it is unclear whether VHA providers are performing guideline concordant testing. It is important to understand oncologists' decision-making processes regarding utilization of genomic testing in the VHA. The VHA population of non-small cell lung cancer patients are primarily smokers, and often have squamous cell carcinoma. Our sense is that testing is done much less commonly in the VHA population than in the population at large because of the characteristics of the patient population and the perception that the tests are unlikely to be positive. We conducted qualitative interviews with VHA-based oncologists to examine their reported utilization of genomic testing for patients with advanced lung cancer.

2. Material and methods

This study was approved by the Michael E. DeBakey Veterans Affairs Medical Center and the Baylor College of Medicine Institutional Review Boards. Our sample of participants was recruited from a list of 218 medical oncologists who practice in the United States VHA. The list was compiled by our project coordinator. We stratified the list by American College of Surgeons Commission on Cancer (COC) accreditation status (yes/no), and we used a stratified purposive sampling technique to recruit participants from each type of facility. Providers were considered for inclusion if they: 1) were specialists in oncology; 2) practiced at the VHA during the time of recruitment; and 3) had experience treating lung cancer in the VHA setting. To recruit our sample of participants, we sent email invitations to the VHA email addresses for 181 medical oncologists. Individuals who accepted the invitation to participate were scheduled via email to take part in a telephone-based interview. We attempted to contact via telephone those individuals who did not accept or decline our initial email invitation. Of those individuals, 103 could not be reached via email or telephone. Of the remaining potential participants, 16 were excluded because they had little experience treating lung cancer, 13 declined to participate, 9 were too busy at the time but were open to interviewing at a later date, 40 agreed to participate, and 30 actually completed interviews. This recruitment strategy was effective in reaching oncologists with reliable contact information listed in the VHA directory. We do not believe that the reliability of the VHA directory posed any problem in terms of selection bias. We were able to recruit a diverse sample of participants and we are confident that the sample accurately represents the population of VHA-based medical oncologists who treat lung cancer. Recruitment and data collection occurred between March 2015 and February 2016.

During recruitment, potential participants were told that the investigators were interested in learning about oncologists' experiences and decisions about using Genomic-Based Targeted Therapy (GBTT) to treat advanced lung cancer in the VHA setting. Participants were scheduled for telephone-based interviews, and verbal consent was obtained prior to all interviews. Interviews lasted between 19 min and 90 min (average 40 min).

Recruitment was stopped at the point of thematic saturation, defined a priori as the point when two independent coders agreed that three consecutive transcripts within a given interview category rendered no new thematic concepts [15,16]. Consistent with Cabana et al.'s theoretical framework, interviews were designed to elicit information about oncologists' knowledge, attitudes, intent to use genomic-based targeted therapy, and perceived facilitators and barriers to using GBTT in the VHA setting [17]. Additional findings are presented elsewhere. The interview guide was pilot tested and revised prior to initiating data collection. All interviews were recorded, transcribed, and analyzed for content. We used Atlas.ti 6.2 to facilitate data analysis and management.

Data were analyzed using framework analysis methodology, which allows for the inclusion of existing concepts as well as emergent themes within a pre-established theoretical framework [18]. Two independent coders with expertise in framework analysis independently created codes and indexed the data using Atlas.ti 6.2. Disagreements about coding decisions were resolved through group consensus. Our coding centered on themes related to oncologists' genomic testing decisions and experiences.

3. Results

We interviewed a total of 30 VHA-based medical oncologists. Participant characteristics appear in Table 1. Interviews revealed oncologists' reports of the frequency at which they order genomic testing in NSCLC patients, as well as factors that shape their likelihood of ordering tests, such as tumor characteristics, evidence, and patient characteristics. Example quotations for each domain appear in Table 2.

3.1. Frequency of testing

Testing frequency varied significantly, ranging from 5%-100% of metastatic non-small-cell adenocarcinoma patients. Several oncologists reported that they would prefer to test 100% of patients, but in practice, test 80%-95%. Others report that they intend to test a small percentage (5%-20%) of their metastatic non-small-cell adenocarcinoma patients. While a very small minority of oncologists report testing "everybody regardless of stage, histology, age, smoking status," (P12), for many oncologists, testing decisions were based on three primary factors: tumor characteristics, evidence, and patient characteristics.

3.2. Tumor characteristics

Oncologists' testing decisions were based primarily on tumor characteristics. Specifically, most oncologists test only patients with adenocarcinoma. A smaller number of oncologists acknowledge testing mixed adeno-squamous pathology. Only a very small minority of oncologists wish to test patients with squamous pathology. Such patients may be tested if patient characteristics indicate they may be a candidate for GBTT. For instance, if a squamous patient has no smoking history, in some cases, an oncologist might elect to send the patient's biopsy for a genomic test.

Tumor stage also plays an important role in testing decisions. The

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