Clinical Trial Participation Linked to Improved Lung Cancer Survival

A related study finds patient and provider perceptions about barriers to trial participation are not in sync.

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Participating in a clinical trial was associated with a nearly 50% decrease in the risk of death for people with advanced non-small-cell lung cancer (NSCLC), according to a study presented at the American Society of Clinical Oncology (ASCO) Quality Care Symposium last week in San Diego.

Another study presented at the meeting showed that providers' beliefs about the benefits of and barriers to clinical trial participation are often not shared by people living with cancer themselves.

"It is our duty as oncologists to enroll our patients in clinical trials when appropriate," Merry-Jennifer Markham, MD, of the University of Florida Health Cancer Center, said in an ASCO press release. "We must work to better understand factors associated with trial enrollment so that the prospective benefits can be made accessible to all who are eligible."

Clinical trials can be a good way to gain early access to promising experimental therapies, but people with cancer often have misconceptions about these studies. Only around 5% to 10% of cancer patients participate in trials, and poor accrual is the leading reason for premature study termination. What's more, trial participants do not reflect the range of people living with cancer, enrolling low proportions of older individuals, people of color and patients with advanced disease.

Improved Survival

Cristina Merkhofer, MD, of Fred Hutchinson Cancer Research Center and the University of Washington, and colleagues assessed the effect of clinical trial participation among people with NSCLC treated at the Seattle Cancer Care Alliance thoracic and head and neck cancer clinic.

This retrospective analysis looked at medical records from 371 eligible patients. Just over half were women, the median age was 64 and a third had never smoked. All had metastatic cancer, including 27% whose cancer had spread to the brain. EGFR and ALK gene mutations, which drive the growth of some lung tumors and can be treated with targeted therapies, were detected in 20% and 8%, respectively.

Of these, 118 people, or 32%, had enrolled in at least one clinical trial, the researchers reported. Women were somewhat more likely to join trials than men, as were people who never smoked compared with current or former smokers.

Among the participants, 89% joined Phase I or II trials (smaller early and mid-stage studies that evaluate safety and preliminary efficacy) while 15% joined Phase III trials (studies in the last stage before approval that test promising therapies in a larger number of people). About one in five (19%) had enrolled in more than one trial.

About a quarter of participants enrolled in randomized controlled trials, in which participants are randomly assigned to receive an experimental therapy or a comparison intervention, usually a competing new drug or the current standard of care. Just over half (51%) took part in trials of drugs that were later approved by the Food and Drug Administration.

The median overall survival was 2.3 years for clinical trial participants compared with 1.2 years for nonparticipants. This represents a 47% reduction in the risk of death after adjusting for other factors, including sex, smoking history, EGFR and ALK status and brain metastasis.

“Participation in therapeutic drug trials is associated with longer overall survival in advanced NSCLC,” the researchers concluded. “Besides supporting drug development, clinical trial participation may directly benefit NSCLC patients by providing access to promising agents and/or enhanced supportive care.”

Attitudes and Beliefs

In the second study, Grace Clarke Hillyer, EdD, MPH, and colleagues from Columbia University’s Herbert Irving Comprehensive Cancer Center looked at barriers to clinical trial enrollment, comparing the attitudes, perceptions and beliefs of providers and patients.

“We found that commonly held beliefs in the research community about why a patient joins or does not join a clinical trial are not in sync with barriers reported by our cancer patients,“ Hillyer said. ”Physicians and staff involved in cancer care and treatment may not be aware of barriers perceived by patients or hold misperceptions about reasons for cancer patients’ reluctance to join a clinical trial that could result in the lack of an offer of a trial to a patient or refusal to join by the patient."

A total of 120 providers and research staff at the center, along with 150 cancer patients not currently enrolled in a trial, completed an online survey in 2017 to assess perceived barriers to enrollment. Providers were asked why their patients did or did not enroll in trials, while people with cancer were asked why they did not do so.

Among the provider/staff respondents, 47 were providers, including physicians (38), fellows (9), physician’s assistants (1) and nurse practitioners (11), while 73 were research staff, including nurses (11) and research coordinators, managers or others (49). Two thirds of provider and staff respondents were women and a majority (63%) were white.

Among the patient respondents, 60% were women, 61% were white, 13% were African American and 29% were Latino. Interviews were conducted in English (117 people) or Spanish (33 people). Half had a college education. About three quarters said they knew what a clinical trial is, 32 people (21%) had ever been invited to join a trial and 21 people (66% of those invited) had done so.

A majority of provider/staff respondents (57%) and patients (69%) said being part of a trial helps people with cancer be more in control of their disease and its treatment, and almost everyone in both groups agreed that trials help advance medical science and clinical care.

Patients had more positive attitudes than providers/staff when asked whether trials offer the best treatment available (60% versus 21%, respectively) and whether the benefits to patients outweigh the risks or harms (57% versus 44%, respectively).

However, patients also had more negative attitudes than providers/staff when asked whether trials are offered only to people whose disease is hopeless (27% versus 9%, respectively) or as a last resort (24% versus 12%) and whether patients who enroll are gambling with their lives (21% versus 11%). Patients were also far more likely than providers/staff to say that being in a trial does not help patients personally (33% versus 2%).

Asked about reasons for joining trials, patients and providers/staff were similarly likely to list getting better treatment (95% and 94%, respectively), having a better chance for a cure (95% and 80%), getting the newest treatments available (91% and 92%), because a doctor recommended it (91% and 84%) and helping people in the future (86% and 80%). Family preference was a less common reason (cited by 33% and 50%). The reason with the widest divergence was feeling like a patient had no better options, cited by 38% of patients and 86% of providers/staff.

Patients themselves gave less weight than providers/staff to most reasons for declining to join a trial, including wanting to use a proven treatment (cited by 46% and 58%, respectively), not wanting to be randomized to less effective treatment or a placebo (37% and 71%), lack of transportation (36% and 45%), mistrust of the medical system (36% and 69%), inconvenience (27% and 59%) and language or cultural barriers (27% and 58%).

Less common barriers included feeling overwhelmed (18% and 64%), possible drug toxicities (18% and 60%), out-of-pocket costs (18% and 37%), family or job responsibilities (18% and 36%), lack of understanding (9% and 63%), concern about invasive procedures (9% and 42%) and lack of insurance (9% and 29%). Lack of interest was the only reason cited by more providers (40%) than patients (34%).

“Understanding gaps in attitudes and perceptions between the cancer care team and cancer patients may lead to the development to more effective interventions to increase clinical trial accrual,” the researchers concluded. They recommended efforts to dispel misperceptions about trials and to improve patient-provider communication.

Click here to read the lung cancer survival abstract.

Click here to read the attitudes and beliefs abstract.

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