Clinical Trials: Does One Size Really Fit All?

Clinical trials in oncology have been instrumental in shaping care. Hundreds of new drugs and other therapeutic strategies have been generated to improve the lives of our patients. Promoting and executing carefully planned and designed clinical trials has been the cornerstone for improving care and for determining the best care. Sometimes we have triumphed and sometimes we have not, but we have always learned something.

As a result, many advocacy groups and professional societies, in their public outreach, stress the importance of participating in clinical trials for patients with cancer. Because of this, some have suggested that if you are not participating in a clinical trial, perhaps you are not getting the best care. Historically, I held that view too. Realistically, of course, there can’t be a trial for every condition, although that would be ideal. Furthermore, now that we’ve entered the genomic era, I am starting to question this philosophy.

Don’t get me wrong: I am not questioning the value of clinical trials, only our approach to educating the public about them. First, if healthcare providers stress that is based on level 1 evidence is, by definition, outstanding care. I try to say instead, “The trials we have open right now are not a good fit for you,” hoping to shift the blame to us. It’s a small thing, but I hope it helps.

Finally, now that we have entered the genomic era, many patients walk in the door with germline testing and somatic molecular profiling already completed. Often these results provide a clue that there is a preferred choice for them among the already established treatments for their condition. For example, I recently saw a new patient who had just learned that he came from a family with *BRCA1* mutations. He underwent testing and found he was a carrier. Because there was pancreatic cancer in the family, he asked for a CT scan, which showed pancreatic cancer metastatic to liver. He asked if we had a clinical trial he could participate in. I explained that we did, but that the chemotherapy backbone of the trial was gemcitabine and albumin-bound paclitaxel. Given the *BRCA1* mutation, he had a higher likelihood of experiencing a response to a platinum-containing regimen, and I advised against the trial. I think these conversations are being had regularly around the world and that these observations inform and improve our care.

So, to conclude, I agree that major progress comes from clinical trials and that all patients should have access to trials. Participation is highly recommended when the trials fit. But maybe we should soften our messaging to the public just a little and reassure them that they can get great care on or off a clinical trial.

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