Genomic Medicine Takes the Stage, Again!

Last month I made my annual pilgrimage to the ASCO Annual Meeting. As usual, I was dazzled (and sometimes frazzled) by the wealth of new information, breakthroughs in oncology care, and vibrancy of our oncology community. What a show!

I was glad to see the results of TAILORx at the Plenary Session. The diagnostic genomic test Oncotype DX from Genomic Health has been used routinely in the clinic for some time to predict the likelihood of recurrence in patients with breast cancer at low risk for recurrence. The TAILORx study was designed to validate the use of the test in patients with early-stage breast cancer at *intermediate* risk for recurrence. Based on its findings, 70% of these patients can safely avoid adjuvant chemotherapy. This is a triumph for patients, for sure. Avoiding chemotherapy and the long-term consequences of treatment is a good thing. It's also a triumph for curbing the cost of care. Obviously, no treatment means no cost. We need a lot more of that!

It stands to reason that in the adjuvant setting, we could probably identify diagnostic tools to predict outcome, and thus need for adjuvant treatment, across all disease sites. Actually, folks are working on that with a fair bit of success. But adjuvant therapy is kind of black or white: you either do it or you don't. In cancer medicine, we have a lot of gray areas, and I sometimes struggle to understand how these will be sorted out.

To me, gray areas are mostly about intensity and duration of therapy. Is 3 or 4 months of adjuvant therapy as good as 6? Can you treat with tyrosine kinase inhibitors intermittently rather than every day? Is a chemotherapy regimen with lots of side effects just as effective if you give lower doses? Does a chemotherapy holiday put a patient at increased risk for progression? These are practical considerations that we face all the time.

For a lot of reasons, we don't seem to have the same appetite for answering these questions. For one thing, our usual structures for clinical trials involve a sponsor with a new product or our federally funded clinical trials network. You would think the latter would take these questions on, and sometimes it does. But not as often as I think it could.

Who are the stakeholders for these gray zones? Certainly the patients who want a good outcome along with an easier path to success are stakeholders, but it seems to me that our payers, including the Centers for Medicare & Medicaid Services (CMS), ought to be pretty enthusiastic about approaches using fewer drugs or with fewer side effects that can also drive down the cost of care. So is it unreasonable to ask them to step forward and support clinical trials to help us answer these questions? Personally, I think it's time for this to happen, and I would hope we could look to CMS for some leadership.

I haven't done the math for any given scenario, but I think that surely certain investments here could reap big rewards. Do you agree? Then let me know!

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doi: 10.6004/jnccn.2018.0063

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