Approved mRNA Vaccines for SARS-CoV-2

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Every new year brings a time for reflection and optimism for what lies ahead. In December 2020, two newly approved mRNA vaccines were approved—BNT162b2 mRNA Covid-19 vaccine (BioNTech/Pfizer) and mRNA-1273 (Moderna/NIAID)—to protect individuals against severe acute respiratory syndrome coronavirus (SARS-CoV-2). As I encounter numerous questions from patients, caregivers, and colleagues regarding these vaccines, I thought I would research this important topic and share some insights with you.

WHAT SHOULD APs KNOW ABOUT THE VACCINES?

The main goal of a vaccine against an infectious agent is to train the body to recognize and digest the virus (CDC, 2020). While the emergency authorization of these two new vaccines may come as a surprise to some, the science behind mRNA technology has been well established. Katalin Karikó, a Hungarian-born scientist, has been studying mRNA technology in a variety of diseases for the past 30 to 40 years. Her research led to the science behind the development of these two vaccines (Anderson et al., 2020).

In both the Pfizer and Moderna vaccines, the active component against the coronavirus infection is a nucleoside-modified messenger RNA (modRNA) encoding the viral spike glycoprotein (S) of SARS-CoV-2. As such, neither vaccine is made from a live virus, which is an important consideration for cancer patients and immunocompromised individuals.

While the Pfizer vaccine must be stored at –70°C for 5 days and at room temperature for 6 hours, the Moderna vaccine can be stored at –20°C and kept in a refrigerator for 30 days (FDA, 2020a, 2020b). Storage issues aside, let's focus on clinical trial results that highlight key safety and efficacy considerations of each vaccine.

CLINICAL TRIAL RESULTS

In the BNT162b2 mRNA Pfizer study, 36,621 patients were included in the primary safety and efficacy analysis. Immunity from COVID-19 was observed almost immediately in the treatment group as more COVID-19 cases accumulated in the placebo group compared with the vaccine group. In addition, 52% vaccine efficacy was observed after a single dose, with overall efficacy at 95%. No serious immediate safety concerns were noted. Injection site reactions (84%),

fatigue (63%), headache (55%), and muscle pain (38%) were cited as the most common side effects and more common after the second dose among individuals younger than 55 years (FDA, 2020a).

In the mRNA-1273 Moderna study, 28,207 patients were included in the primary efficacy analysis of COVID-19 disease at 14 days after the second dose (Anderson et al., 2020). The overall response rate was 94.5%, with similar safety concerns of injection site reactions (91%), fatigue (68%), headache (63%), and muscle pain (59%). Four cases of Bell's palsy occurred between days 22 and 28 (3 vaccine, 1 placebo). The only contraindication for either vaccine is among patients with a history of severe allergic reaction (i.e., anaphylaxis) to any vaccine component (FDA, 2020b).

WHAT DO THESE RESULTS MEAN FOR PATIENTS WITH CANCER?

In each study, patients who were receiving ongoing chemotherapy or immunotherapy were excluded from the trials. That being said, smaller analyses from ongoing trials and expert opinion have suggested no new safety concerns among older individuals or those with chronic health conditions, and that either vaccine should be offered to anyone who is willing (Anderson et al., 2020; Walsh et al., 2020).

The coronavirus has undoubtedly affected many cancer patients in some way, either through interrupted care, delayed office appointments, or a necessitated switch to telehealth. The two approved vaccines appear to be relatively safe for cancer patients, with low rates of immunogenicity and anaphylaxis, and a low risk of serious safety concerns.

Vaccine hesitancy is a real concern among health-care workers and patients alike. In my practice, I will share the data to support the safety of these vaccines with patients. I will encourage vaccination of all patients and household contacts who have access to a vaccine and do not display evidence of acute infection or illness.

For those who do not want to receive a vaccine, I will highlight the importance of good hand washing, effective mask wearing, and physical distancing. I am sure you will all continue in support of our communities in the best way possible for the duration of this pandemic.

IN THIS ISSUE

For those of you drawn to learn about updates in hematologic cancers, Drawdy and colleagues review the impact of adherence to ibrutinib on clinical outcomes in real-world patients with chronic lymphocytic leukemia (CLL). Goodrich provides updates in a CE-certified article on preventing and managing tumor lysis syndrome and neutropenia in CLL, two important oncologic emergencies.

Relevant to all advanced practitioners (APs) in oncology, Goswami discusses advance care planning and end-of-life communication. In our Research & Scholarship section, Seaborne and colleagues describe a women's integrative sexual health program. Our oncology AP colleagues share updates in metastatic melanoma, metastatic breast cancer, thoracic surgical oncology, and diagnosing liver cancer.

In closing, I would like to extend my sincerest thanks to all of JADPRO's peer reviewers, section editors, and editorial staff. And many thanks to each of you for choosing to be a part of this JADPRO and APSHO community, with continued wishes of health and happiness, in 2021 and beyond.

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