COVID-19 vaccine fast facts

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Clinical question

What are the benefits and risks of 3 coronavirus disease 2019 (COVID-19) vaccines?

Bottom line

Interim results (2 large RCTs) show the relative efficacy of the Pfizer-BioNTech and Moderna vaccines (about 95%) and the AstraZeneca-Oxford vaccine (about 70%) in preventing COVID-19. Absolute benefits will vary with baseline risk and time: if the annual risk of developing COVID-19 is 20%, then the vaccine would decrease the risk to 1% (6% with the AstraZeneca-Oxford vaccine). These vaccines appear safe and might decrease the likelihood of severe COVID-19. Ongoing studies should provide further details.

Evidence

Interim results are from US Food and Drug Administration[1,2] or peer-reviewed publications (median follow-up of 2 months).[3-5] The cases were symptomatic and had laboratory-confirmed COVID-19.[5-7] Severe COVID-19 was defined as needing high-flow oxygen or intensive care unit admission.[5-7] All relative risk reductions (RRRs) are statistically different.

- Pfizer-BioNTech: In 1 double-blind, multi-country RCT (N = 40 137; median age of 51),[1,3,6] 2 doses were given 21 days apart.[1,3] The vaccine arm had 9 COVID-19 cases (1 severe) and the placebo arm had 169 cases (4 severe; RRR = 95%).[3]
  - -Unsolicited reported adverse events (AEs)[1] included injection pain (11%), fatigue (6%), and myalgia or headache (5%). Solicited specific AEs yielded 5 to 10 times more responses (eg, fatigue reported in 34% to 59% of patients in the vaccine arm; 17% to 33% in the placebo arm).[1,3] Incidence of serious adverse events (SAEs; about 0.5%) and incidence of deaths were similar between arms.[1,3]
- Moderna: In 1 double-blind RCT (N = 28 207; median age of 51),[2,5,7] 2 doses were given 28 days apart.[2,5] The vaccine arm had 11 COVID-19 cases (0 severe) and the placebo arm had 185 cases (30 severe; RRR = 94%).
  - -Unsolicited reported AEs[2] included headache (3%), fatigue (2%), lymphadenopathy (1.2%), and myalgia (1%). Solicited specific AEs yielded 5 to 20 times more responses (eg, headache was reported in 25% to 63% of patients in the vaccine arm; 18% to 29% in the placebo arm). Incidence of SAEs (0.6%) and incidence of deaths were similar between arms.
- AstraZeneca-Oxford: In 4 RCTs (N = 11 636) with multiple arms (including variable first dose and timing [4 to > 12 weeks] of second dose), 2 doses were given.[4,8] The vaccine group had 30 COVID-19 cases (0 severe) and the placebo group had 101 cases (2 severe; RRR = 70%).[4]
  - -There was a lower RRR in the standard-dose regimen compared to the low-dose regimen (62% vs 90%). The low dose was given only to those between 18 and 55 years of age (roughly 90% health care workers).
  - -The vaccine group had 0.7% SAEs compared to 0.8% in the placebo group.[4] There were 3 cases of transverse myelitis (2 cases with vaccine; 1 case with placebo), but were deemed unrelated to the vaccine.[4] Overall mortality is similar between groups.[4]
- Limitations: unknown efficacy in children and unknown duration of response.

Context

- Storage requirements[4,9,10]: Pfizer, -70°C; Moderna, -20°C; and AstraZeneca-Oxford, 2°C to 8°C.
- Baseline risk of COVID-19 varies substantially with location and time, affecting potential absolute benefit (eg, if annual risk is 20%, Pfizer or Moderna vaccine decreases risk to 1% and AstraZeneca-Oxford to 6%).

Implementation

Preparation and administration requirements differ considerably.[11-13] Anaphylaxis was a reported AE after Pfizer vaccine administration in about 1 per 90 000 doses, and in about 1 per 400 000 after Moderna vaccine administration; about 80% to 90% of anaphylactic patients had history of allergies or anaphylaxis.[14,15]

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Competing interests
None declared

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