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Short communication

Specialist confirmed allergic reactions to COVID-19 mRNA vaccines at a mass vaccination site

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ABSTRACT

Healthcare providers can play a key role in reaching the target for vaccine uptake through educating the public on the risk may be of severe allergic reactions to COVID-19 vaccines. Thus, it is important to resolve reports in the literature which present conflicting data on vaccine safety. We performed a prospective study of Pfizer-BioNTech vaccinations administered at the Albany Community Vaccination Center. All potential vaccinees to the site were screened for allergic history prior to triage by a board-certified allergist. In the first 14 days of operation, our site vaccinated 14,655 individuals, 3.9% of which had a personal history of anaphylaxis. While some vaccine recipients had non-allergic complications, none of the visitors suffered any objective, immediate allergic symptoms. Our findings indicate that specialist-confirmed rates of immediate allergic reaction to mRNA SARS-CoV-2 vaccination are far lower than self-reported rates defined by subjective, unconfirmed symptoms.

1. Introduction

With the emergency use authorization of several vaccines against the SARS-CoV-2 virus the potential end of the pandemic seems within sight. Healthcare providers, especially allergists, can play a key role in reaching the target for vaccine uptake for individuals through educating the public on the reported risk of severe allergic reactions to these vaccines. Thus, it is important to resolve reports in the literature which present conflicting data on vaccine safety. Recently, Blumenthal et al reported their prospective assessment of the rate of anaphylaxis in 64,900 health care employees receiving a first dose of either the Moderna or Pfizer-BioNTech SARS-CoV-2 mRNA vaccine[1]. However, their methodology could overestimate anaphylaxis to a degree that may stimulate fear and decrease uptake in an era of vaccine hesitancy [2,3]. Using self-reporting surveys and evaluation periods lasting beyond the usual time period of immediate hypersensitivity reactions, the authors calculated an overall rate of anaphylaxis of 2.47 per 10,000 injections; a rate nearly two orders of magnitude greater than the rate reported to the CDC by clinicians through the Vaccine Adverse Event Reporting System (VAERS)[4]. This rate would extrapolate to over 30,000 cases of anaphylaxis for the first 150 million vaccinations given, yet this number of anaphylaxis cases after vaccination was not reported. The population defined as high-risk in this study (due to prior history of severe allergic reactions to foods, medications, or vaccines) was estimated by the authors, rather than calculated, and reported as 4000/64900 (6%). A program that could offer a real-time, prospective evaluation of allergic reactions in a diverse community could greatly add to the understanding of the risk of allergic reaction to mRNA SARS-CoV-2 vaccination.

2. Methods

We performed a prospective study of Pfizer-BioNTech vaccinations administered at the Albany Community Vaccination Center. Our population was 63.1% White, 8% Black, 6.2% Asian/Pacific Islander, 18.3% unspecified, and 5% Hispanic; with 33% in the highest anaphylaxis incidence age range of 16–39 years [5] (Table 1). At the time of our evaluation, the state of New York set eligibility by zip code; within the eligible zip codes registrants needed to be either over 60 years of age, have documented immune deficiency, be a health care worker, or work as an educator.

Potential vaccine recipients could drive or take a bus to the Albany Washington Avenue Armory, a historic building that was once the home of the Army's Tenth Battalion but now is used as a church and basketball arena for the Albany Patroon of the Conti-

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Table 1
Characteristic of vaccinees with descriptions and enumeration of complications are presented.

Demographics	N	%
Total	14,655	100
Any reported history of severe allergic reaction	581	3.9
Denied vaccination (any reason)	0	0
Race		
American Indian/Alaskan Native	30	0.2
Asian/Pacific Islander	914	6.2
Black	1,168	8.0
Multiracial	243	1.6
White	9,243	63.1
Other	382	2.6
Unspecified	2,675	18.3
Ethnicity		
Hispanic	662	4.5
Non-Hispanic	10,059	68.6
Unspecified	3,934	26.8
Age		
16-40 years	4,836	33
41-64 years	7,225	49.3
>65 years	2,594	17.7
Potentially allergic symptoms		
Rash, any	2	0.013
Hives	0	0
Respiratory/Chest	0	0
Lightheadedness	7	0.048
Gastrointestinal distress	3	0.02
Oral Symptoms (tingling, numbness, swelling, or other around lips, tongue, or mouth)	5	0.034
Two of above at once	1[a]	0.006
Anaphylaxis	0	0
Non-allergic complications		
Any (requiring additional medical evaluation)	27	0.18
Serious (requiring EMS transport)	4	0.027

a)Emesis and light headedness. No other symptoms, vitals stable. Self-resolved after 15 minutes without treatment.

nental Basketball Association (Fig. 1A). Upon entry, visitors received all necessary informational handouts on the vaccine prior to check-in and/or onsite registration. After each had provided documentation of written informed consent, they were taken to individual cubicles to provide verbal consent (Fig. 1B). Prior to any vaccination, all potential vaccinees to the site were screened for allergic history prior to triage by a board-certified allergist. If cleared, they were vaccinated and then monitored for either 15 min (for low-risk groups) or 30 min (for those with a personal history of anaphylaxis).

3. Results

In New York, some vaccinees presented with physician letters identifying a history of anaphylaxis as an immune defect meeting eligibility criterion for vaccination priority; therefore, 3.9% of this enriched atopic population had a personal history of anaphylaxis (Table 1); this rate is below the reported lifetime anaphylaxis risk of 7.7% defined in retrospective analyses, but greater than the 1.6% lifetime risk established as a more rigorous definition[6]. 14,655 vaccinations were performed over the first 14 days without a single case of anaphylaxis (Table 1). One patient reported symptoms from two organ systems, which included one bout of emesis and lightheadedness lasting less than 15 min.

While no individuals required emergent care for allergic symptoms, four were transported to the local hospital for non-allergic complaints: one patient who reported an untreated seizure disorder had a witnessed seizure, but no vital sign abnormalities or other symptoms; a 49 year old male reported 30 min of isolated left arm tingling after injection in left arm but no other signs of acute coronary syndrome, but in an abundance of caution was transported to rule out myocardial infarction; a 70 year old male with known heart block and previously scheduled for a pacemaker insertion reported feeling weak and had second degree, type II heart block on the heart monitor, while his rhythm stabilized at a pulse over 70 he was sent for pacemaker insertion; and lastly a 45 year old female with no allergic history reported lightheadedness had normal vitals and no other symptoms, was transported when symptoms did not resolve in 30 min but was discharged after an additional hour of observation and symptom resolution without need for treatment.

4. Discussion

Despite 3.9% of vaccine recipients reporting a history of anaphylaxis, no anaphylactic reactions to COVID-19 mRNA vaccines occurred among 14,655 vaccinations. Both our findings and those reported by Blumenthal et al cannot account for high-risk patients that were screened out by their primary care or allergy providers. In theory, some subjects with a history of anaphylaxis may have chosen not to receive or been advised against receiving a COVID-19 vaccine. While we cannot exclude this confounder, at least one individual presented to our site with documented hereditary alpha tryptasema [7]; she reported over 25 incidences of anaphylaxis in her life (none to prior vaccines) but was still safely vaccinated and sent home after 60 min of monitoring. Thus, our findings of no anaphylactic reactions among a large group of vaccine recipients whom were assessed in real-time by a specialist are in alignment with the CDC reported rate of anaphylaxis being 2.4–4.5 per million vaccinations [4] as well as the complication rates reported during the clinical trials [8].

5. Conclusions

The report by Blumenthal et al must be interpreted in the light of its acknowledged limitation of self-reporting and should be both interpreted cautiously and contextualized appropriately against

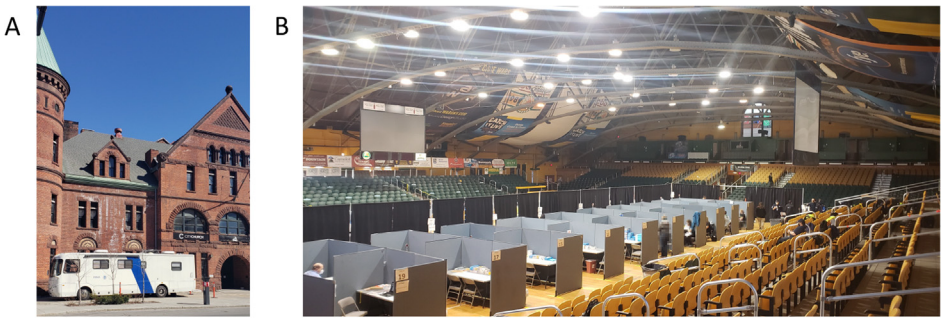

Fig. 1. Images of vaccination site. A. Outside image of Washington Avenue Armory front entrance in Albany, New York with command truck from Federal Emergency Management Agency (FEMA). B. Internal image showing the cubicles for vaccination in basketball arena.

the evidence of safety for the ongoing mass vaccination campaign. Given that reductions in the reported incidence of major side effects is associated with a 4% increase in willingness to receive the COVID-19 vaccine [2], overstated risks are not without potential real-world consequences. The higher rate reported by Blumenthal may be due to their study design being reliant on self-reporting and allowing symptoms that presented 3 days after vaccination to be considered a sign of anaphylaxis. When assessed in real-time by an allergist, no immediate allergic reactions were found when a large group of vaccine recipients from diverse backgrounds, even in the presence of a history of anaphylaxis. Our results are consistent with previously reported data [4,8] and is reassuring regarding the overall safety of the vaccines.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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