Original Article

A Study to Describe the Pattern of Cutaneous Adverse Effects of COVID-19 Vaccines (Covishield and Covaxin)

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Abstract

Background: Vigorous administration of COVID-19 vaccines to tackle the ongoing pandemic has led to increasing research on adverse effects including both systemic and cutaneous. **Objective:** A prospective observational study to delineate the cutaneous adverse effects of two vaccines, namely Covishield and Covaxin, administered in two doses in northern India. **Materials and Methods:** The study was conducted in a tertiary hospital in northern India wherein patients were asked to report voluntarily any cutaneous adverse effects after COVID-19 vaccination to the dermatology department. The data were collected using excel sheets and later analyzed taking into consideration the age, vaccine types, and duration of onset of adverse effects. **Results:** Of the 19,672 vaccination jabs, 296 (1.5%) developed cutaneous adverse effects of which the incidence was higher in Covishield vaccine group compared to Covaxin vaccine group. The incidence of side effects was more with the first dose of either vaccine compared to the second dose. All the side effects were benign and were managed symptomatically or were self-limiting. **Limitations:** The number of vaccine recipients was limited and there was a considerable overlap of adverse effects with both vaccines. Voluntary reporting of cases is not an accurate representation of the scale of patients with adverse effects. **Conclusion:** Rampant administration of vaccines along with widespread advertisement of vaccine-induced side effects via social media has created apprehension in the general population. This warrants studies improving awareness about the most vital preventive measure available to halt and eventually end the COVID-19 pandemic.

Keywords: *Chill blain-like lesions, Covaxin, COVID-19, Covishield, injection site reactions, m-RNA vaccine, vaccine-induced adverse effects*

Introduction

The first known case of severe acute respiratory syndrome caused by SARS-CoV-2 virus was reported in December 2019 from Wuhan city, China. The infection spread exponentially all across the world, claiming many lives. The contagious nature of the disease associated with high morbidity and mortality alarmed the world and prompted multifaceted research, among which developing a novel vaccine was one. Both well-established and experimental vaccine platforms were created and over a year later, several safe and efficacious vaccines were administered all over the world.[1] The vaccines licensed for mass immunization campaigns are nucleic acid–based vaccinations, viral vector products, and inactivated viruses. Protein subunit vaccines are not yet included in these campaigns. In the face of the ongoing pandemic, there is a pressing need for mass immunization and substantial regional variation is seen in the usage of the type of platform used. While developed countries have immunized a wide majority of their population, other countries still are catching up due to a lack of resources.[2] Vaccines are known to have cutaneous adverse effects in the past which can be understood by the fact that many viral illnesses have cutaneous eruptions like measles, herpes simplex virus, hepatitis B virus, and parvovirus B 19. SARS-CoV-2 viral infection itself has been shown to have cutaneous manifestations like exanthematous, vesicular, chill-blain-like (CLL) lesions, and urticarial rash. Keeping the same pathophysiology in mind, COVID-19 vaccination-related cutaneous adverse effects can also be understood which include widespread rash, erythema, CLL lesions, urticaria, and many more. Many have only recently started

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describing the cutaneous adverse effects of this vaccination, while earlier studies could not accurately describe them from the perspective of a dermatologist. In this study, we included only those cases that were available for long-term follow-up and could be easily traced if required as most of the patients were healthcare workers.[3,4] In the present study, we want to draw attention to the myriad of cutaneous adverse effects post–COVID-19 vaccination, their morphology, persistence, and recurrence over one year to have a better understanding of these events.

Materials and Methods

The study was conducted in a tertiary care hospital in northern India after the outbreak of COVID-19 in 2020 and 2021. Institutional ethical committee consent was obtained before starting the study. The participants were healthcare workers which included doctors, paramedics, and others involved in healthcare directly or indirectly and a defined population that could be followed up. All the patients aged more than 18 years and who were to be vaccinated were approached to participate in the study. Participants were either vaccinated with SARS-CoV-2 antigen strain NIV-2020-770 manufactured by Bharat Bio-tech (Covaxin) or ChAdOx1-S recombinant monovalent vaccine manufactured by AstraZeneca (Covishield). All the patients were briefed about the nature and objective of the study and about the possible cutaneous adverse effects postvaccination. Representative images of such adverse effects were shown to them via posters displayed in vaccination centers and through social media to sensitize them. In case of such events, patients were directed to self-report to the vaccination center, emergency room, or dermatology outpatient department, or to seek teleconsultation through video call, WhatsApp images, or text messages, whichever was convenient. The participants were briefed to note the interval between the administration of the COVID-19 vaccine and the onset of the cutaneous adverse effects and to note the persistence and recurrence. All the patients in whom the dermatological examination could not be carried out due to unavailability of images or patients unwilling to report physically were excluded from the study. A total of 19,672 vaccine administrations were studied during this period where each jab was counted as one. A patient who had both doses was counted as two separate administrations. A total of 12,196 (62%) jabs of Covishield vaccine were administered and 7,476 (38%) were given Covaxin jabs. On reporting, the type of cutaneous adverse effects, its onset, and progression were individually assessed by two independent dermatologists and demographic data were also endorsed. The patients were followed up intervally by telephonically contacting individual patients and to report to the dermatology outpatient department if needed. Statistical analysis was performed using software packages SPSS (Version 16, Chicago IL, USA) and MS Excel sheets were used to tabulate findings.

Results

A total of 296 cases were studied over a period of 12 months from June 2021 to May 2022. Of which, majority of the study participants were males (86.5%, 256), while females constituted 13.5% (40). The most common age group affected was between 18 and 30 years where 102 (34.4%) patients developed cutaneous adverse effects due to vaccination followed by 86 (29%) in the age group of 31-45 years. Detailed distribution as per age and gender of the patients is illustrated in Table 1. Among those who developed adverse effects, Covishield was administered to 246 (83.1%) compared to Covaxin administration to 50 (16.9%) participants. Injection site reaction was the most common adverse effect seen in 121 (40.9%) patients. Injection site reaction was more commonly seen after Covishied vaccine in 94 (31.7%) cases as compared to 27 (9.1%) who developed it after Covaxin administration. The reaction was more commonly seen within 6 hours in 92 (31.08%) patients. The reaction was more common after the second dose of either vaccine. The other relevant details of the duration, distribution, and pattern of the adverse effect are depicted in Tables 2 and 3. Eleven (3.7%) patients had injection site reaction after both doses of Covishield while three (1%) developed after both shots of Covaxin. Exanthematous/Morbilliform rash was the second most common adverse effect seen in 60 (20.2%) patients. Again it was more frequently associated with Covishied injection in 54 (18.2%) patients. Of 54 patients, 49 (16.5%) reported this rash after the first dose of Covishied, while 5 (1.7%) developed it after the second dose of Covishied. Only two (0.7%) cases reported morbilliform after the first, while four (1.4%) after the second dose of Covaxin injection. Urticarial rash, petechiae/purpura, CLL lesions [Figure 1], and other adverse effects and their distribution are represented in Tables 2 and 3. Aggravation of pre-existing psoriasis vulgaris [Figure 2] was reported in one (0.3%) patient after one week of the first dose of Covishield injection where the patient was in remission. Precipitation of Type 1 lepra reaction was seen in three (1%) patients in the form of increased erythema, appearance of new patches, and neuritis. Only one patient had precipitation of Type 2 lepra reaction after the first dose of Covishield.

Discussion

COVID-19 pandemic since its first reported case on December 2019 has changed various facets of the conduct

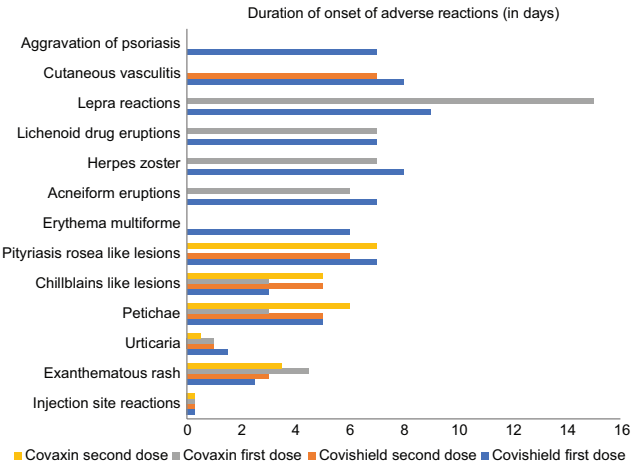
Table 1: Demographic data

Age (in years)	Males	Females	Total
18-30	88	14	102
31-45	80	06	86
46-60	21	11	32
61-75	54	07	61
>75	14	01	15

Table 2: Frequency of adverse effects

Adverse effect	Frequency	Percentage	Covishield (Frequency)		Covaxin (Frequency)		Covishield		Covaxin	
			First dose	Second dose	First dose	Second dose	First dose Median duration of onset (in days)	Second dose Median duration of onset (in days)	First dose Median duration of onset (in days)	Second dose Median duration of onset (in days)
Dermatological adverse effects										
Injection site reactions (a)										
a1(<6 hrs)	92	31.08	21	51	5	15	3.5 hrs	3.5 hrs	3 hrs	3 hrs
a2 (6-24 hrs)	25	8.4	6	13	1	5	12 hrs	12 hrs	14.5 hrs	16 hrs
a3(>24 hrs)	4	1.4	1	2	1	0	1.5	2	2.5	0
Exanthematous rash	60	20.2	49	5	2	4	2.5	3	4.5	3.5
Urticaria (b)										
b1(<6 hrs)	5	1.7	5	0	0	0	3.5 hrs	0	0	0
b2 (6-24 hrs)	30	10.1	23	6	0	1	12 hrs	15.5 hrs	0	12 hrs
b3(>24 hrs)	0	0	0	0	0	0	0	0	0	0
Petichae/purpura	23	7.7	8	12	2	1	6	3	5	5
Chill blains like lesions	16	5.4	9	2	2	3	3	5	3	5
Pityriasis rosea like lesions	11	3.7	5	3	0	3	7	6	0	7
Erythema multiforme	6	2.0	4	2	0	0	6	5	0	0
Acneiform eruptions	6	2.0	4	0	2	0	7	0	6	0
Herpes zoster	5	1.7	4	0	1	0	8	0	7	0
Lichenoid drug eruptions	4	1.4	3	0	1	0	7	0	7	0
Cutaneous vasculitis	4	1.4	3	1	0	0	8	7	0	0
Lepra reactions										
Type I	3	1.0	2	0	1	0	12	0	15	0
Type II	1	0.3	1	0	0	0	7	0	0	0
Aggravation of pre-existing dermatoses										
Aggravation of psoriasis	1	0.3	1	0	0	0	7	0	0	0
Total	296	100	149	97	18	32				

Table 3: Duration of adverse effects



of medical practice. As numerous research studies are being done to ascertain its epidemiology, clinical manifestations, management, and prevention, vaccination against the SARS-CoV-2 virus is among the most studied aspect.[1,4] SARS-CoV-2 antigen strain NIV-2020-770 manufactured by Bharat Bio-tech (Covaxin) and ChAdOx1-S recombinant monovalent vaccine manufactured by AstraZeneca (Covishield) are the two most commonly administered vaccines in India. Injection site reactions, exanthematous rash, urticaria, pernio-like lesions, erythema multiforme (EM), pityriasis rosea (PR), purpura, livedo reticularis-like lesions, and aggravation of pre-existing dermatoses are the most common vaccine-related adverse effects reported in the literature. Also, cutaneous lesions are noted in postvaccination multisystem inflammatory syndrome (MIS). MIS is common with whole virus vaccine owing to IgG-mediated immune dysregulation. Aluminium hydroxide used as adjuvant can also be an additional culprit. Symptoms pertaining to hypotension and cardiac dysfunction begin 2-5 weeks after both the disease and postvaccination. A solitary case of mRNA vaccine-induced MIS has also been reported in the literature.[5,6] The main focus was to test the efficacy of the vaccine rather than the side effects that can be a bias in assessing vaccine side effects. Most of the adverse effects were benign and self-limiting and recipients were encouraged to complete their vaccine schedules despite this hindrance. No severe cutaneous adverse effects were recorded. On the other

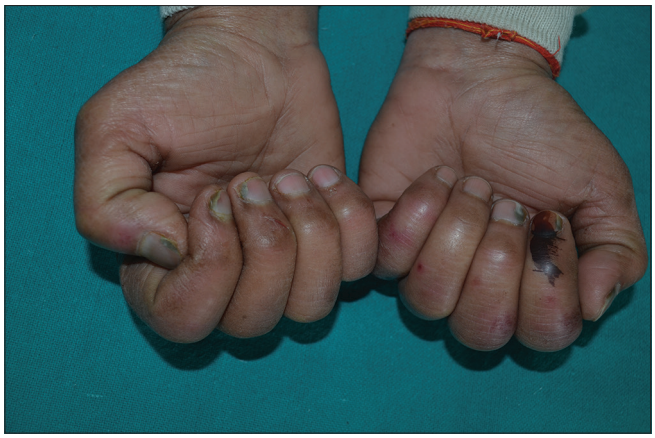


Figure 1: Chill blain like lesions following Covishield vaccine

hand, numerous misconceptions have crept into the minds of the general public as a result of social media entailing awareness about these adverse effects.[7]

Various studies conducted in the Indian subcontinent conclude that Covishield vaccine is responsible for the majority of side effects, and there was also a significant skewing toward the first dose of vaccination. Adverse effects were nonetheless reported from all other vaccines including Covaxin and Sputnik-V vaccine. Among the various vaccines administered across the globe, 78% of adverse effects occur following recombinant vaccines, 18% after adenoviral vector vaccines, and 2.5% following administration of whole virus-inactivated vaccines. A web-based study done by Sil *et al.* included 443 patients which were administered the same vaccines as the index study. Injection site reactions, urticaria, and morbilliform rash were the most common adverse effects which were similar to our study. Telogen effluvium and aphthous ulcer were adverse effects in the study which were not observed in our study. Present study was done to bridge the gaps in our knowledge of cutaneous adverse effects due to two most frequently used COVID-19 vaccines in the Indian population as most of the current literature available is from outside the Indian subcontinent.[8]

In our study, a total of 12,196 (62%) jabs of Covishield vaccine were administered and 7,476 (38%) were given Covaxin jabs constituting 19,672 total vaccine administrations. A total of 296 (1.5%) patients developed cutaneous adverse effects to COVID-19 vaccines. Tan *et al.* reported an incident of 1.6% of the total 58,000 vaccinated population, while Catala *et al.* had an estimated incidence of 1.8%. Both these studies are in coherence with the finding of the present study.[9,10] In the present study, 256 males were more commonly affected (86.5%) as compared to 40 (13.5%) females. This finding is in contrast to the findings of the study conducted by Rerknimitr *et al.* where 169 (82.84%) and 27 (75%) females developed cutaneous adverse effects to Sinovac and AstraZeneca injections, respectively.[11]

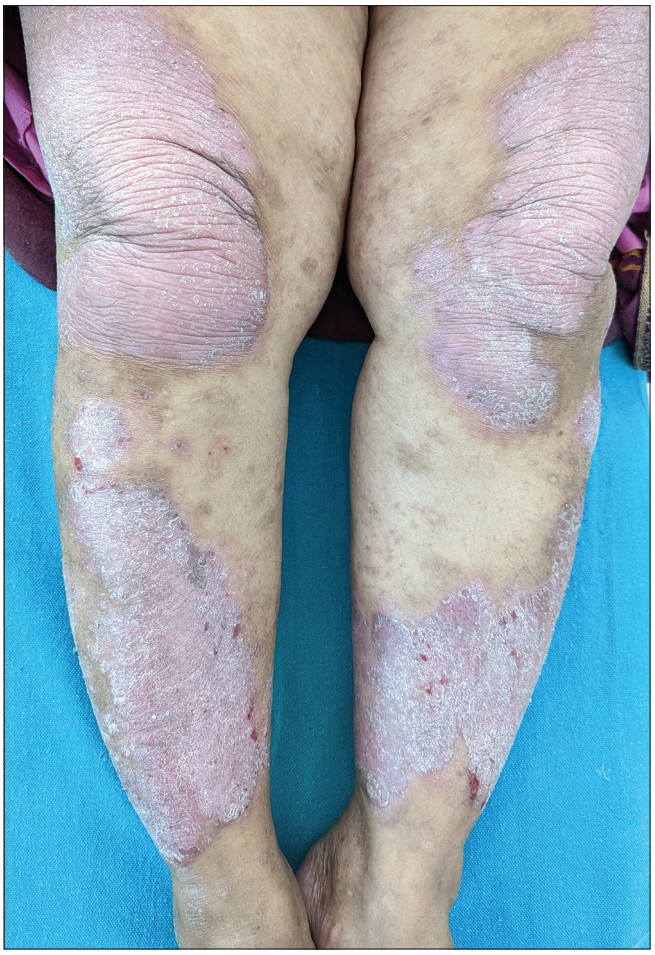


Figure 2: Psoriasiform lesions following Covishield vaccine

This deviation can be due to the specificity in population dynamics of our study.

Injection site reactions were the most common cutaneous adverse effect in the present study, while urticaria was the most common cutaneous adverse effect in the study done by Rerknimitr *et al*.[11] However, Mc Mohan *et al.* also reported injection site reactions as the most common cutaneous adverse effect in their study.[2] Similarly, Menni *et al.* also reported localized skin redness, tenderness, and swelling as the most common local reaction which is in alignment with our study.[12] In the present study, injection site reactions were more common with Covishied as compared to Covaxin and also most of the reactions were seen after the second dose of Covishied which is similar to the findings of Bawane *et al*.[6] Eleven (3.7%) patients developed injection site reaction after both first and second dose of Covishied, while three (1%) had after both the doses of Covaxin.[6]

Exanthematous/Morbilliform rash was the second most common cutaneous adverse effect seen in the present study. Similar findings are reported in the study conducted by Menni *et al.* and Rerknimitr *et al*.[11,12]

Urticaria was seen more commonly after Covishield first dose. The onset was between 6 and 12 hours in 23 (7.7%)

cases after the first dose of Covishield, while only one patient developed urticaria within 6-12 hours of the second dose of Covishield. Bawane *et al.* reported urticaria more commonly after the first dose of Covishield, while no patient developed urticaria after Covaxin administration.[6] Urticarial vasculitis was seen in three (1%) cases after the first dose of Covishield, while one patient had it after second dose of Covishield. Covaxin was not associated with urticarial rash in the study.

Petechiae/ecchymoses/purpura, like in the present study, has also been reported by Mcmohan *et al.* and Rerknimitr *et al*.[2,11] Covishied resulted in petechiae after firstdose in three (8.82%) cases, while none of the patients reported it after the second dose in the study by Rerknimitr *et al*. In the present study, eight patients had this adverse effect after the first dose of Covishield, while 12 developed after the second dose. Three cases had a petechial rash after both shots of Covishield. Only two patients developed petechiae after the first dose of Covaxin as compared to one after the second shot.[11]

CLL lesions are reported in association with COVID-19 pandemic already. Detection of SARS-CoV-2 within the lesions with immunohistochemistry and electron microscopy is done by some authors. CLLs recently have also been reported after m-RNA vaccinations for COVID-19. In our study, CLLs after both Covishield and Covaxin administration were more common after the first dose of Covishield. One patient in both the vaccination group had CLL after both the first and second shot. All the patients developed CLL within 3 to 5 days of vaccine administration. None of these patients had any other associated symptoms and the symptoms subsided on their own in 3-4 weeks. Similar findings have been reported by Russo *et al*.[13]

PR is another adverse effect seen by some authors after COVID-19 vaccination. In the present study, PR-like lesions were seen after both Covishield and Covaxin. All the patients in the present study developed PR-like lesions within 4 days to 15 days of duration. PR-like lesions have already been reported with a second dose of Pfizer BioNTech vaccine as reported by Busto-Leis Negre *et al.* which is again consistent with the findings in the present study.[14]

Six patients developed target lesions suggestive of EM [Figure 3]. All the patients reported these lesions after administration of Covishield vaccination and none of the patients on Covaxin had the same complaints. The first dose of Covishield was more commonly associated with EM-like lesions. Our findings are consistent with the findings of Rerknimitr *et al*. Two of these patients had associated mucosal involvement, while the other had only skin lesions.[11]

Other rare adverse effects like acneiform eruptions, lichenoid drug eruptions, and herpes zoster (HZ) have also been reported after COVID-19 vaccination.[15,16] HZ was mostly seen from 3 days to 10 days of the vaccination in all the cases. Development of HZ-like lesions although not fully understood, may be attributed to Toll-like receptors 3 and 7 stimulation by m-RNA vaccines.[17-20]

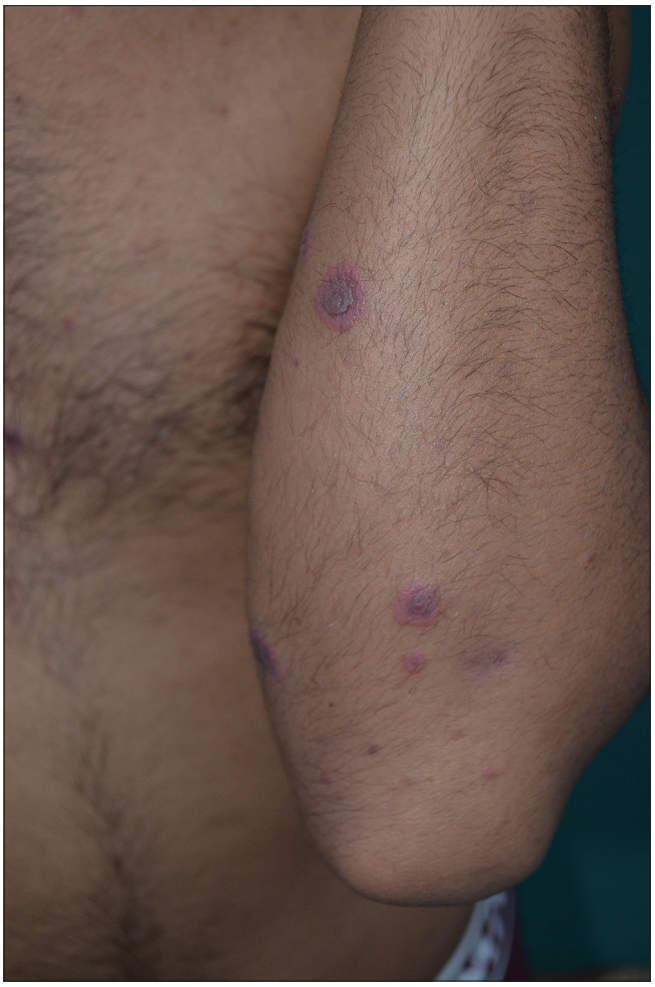


Figure 3: Classical erythema multiforme lesions following Covishield vaccine

Exacerbation of pre-existing psoriasis after COVID-19 has been established recently. In an international registry of 414 cases who developed cutaneous reactions post Pfizer-BioNTerch and moderna vaccines, two cases had an acute exacerbation. The average interval reported for exacerbation was 10 days. We found only one case of psoriasis in exacerbation after 7 days post the first dose of Covishield. The patient was on topical therapy and was in remission before the vaccination. He had exacerbation of the psoriatic plaques which progressed to involve around 15%-20% of body surface area. There was no arthritis. The patient was managed with narrow band ultraviolet-B therapy with good improvement. However, we suggest a study on a large number of patients to establish the association between COVID-19 vaccination and exacerbation of psoriasis.[2,21,22]

Precipitation of type 1 lepra reaction was seen in three patients, while one patient had type 2 lepra reaction. Type 1 reaction was seen after first dose of Covishield vaccination in two patients, while one developed it after the first dose of Covaxin. Type 2 reaction was seen after the first dose of Covishield. We have already reported cases of neuritis and nerve abscess following COVID-19 vaccination in the past from the same center.[23,24]

Conclusion

COVID-19 vaccines, akin to the virus, can alter the immune system, rarely resulting in adverse reactions. The patho-mechanisms are different and every novel research brings a specific facet to light. A widespread social media advertisement of the virus has resulted in undue apprehension in the general population about whether to get vaccinated or not. Hence, it is imperative that awareness about the actual incidence of adverse effects will combat this apprehension and the vaccination campaign will get a significant push. Dermatologists are actively involved in the management of adverse drug reactions and should be vigilant in counselling about these reactions to aptly tackle the pandemic.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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