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Self-Reported Adverse Reactions to COVID-19 Vaccines Among International Travelers Entering Australia

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ABSTRACT

Objective: This study aimed to describe the self-reported adverse reactions following COVID-19 vaccination among international travelers entering Australia and to examine associations between reported reactions and vaccine type, demographic factors, comorbidity, and prior COVID-19 infection.
Methods: A cross-sectional online survey was conducted among 1,435 international travelers arriving in Australia between April and November 2022 who had received at least one dose of a COVID-19 vaccine overseas. Adverse reactions were self-reported via a validated questionnaire administered through Google Forms. Severity was rated on an 11-point numerical rating scale and categorised a priori as mild (1–3), moderate (4–6), or severe (7–10). Associations with demographic and clinical factors were assessed using chi-square tests (crude ORs) and binary logistic regression (adjusted ORs), stratified by vaccine type.
Results: Overall, 947 participants (65.9%) reported at least one adverse reaction. The most common symptoms were injection-site pain (47.2%), fatigue (22.8%), headache (18.0%), and myalgia (11.5%). The majority of reactions were mild (93.0%), and 74.1% of affected participants required no medical care. Pfizer-BioNTech recipients reported significantly more adverse reactions per person than Sinopharm recipients (2.48 ± 2.27 vs 1.72 ± 1.79; $p < 0.001$; crude OR 1.28; 95% CI 1.05–1.56). First-dose reactions were more frequent with Sinopharm, while second-dose reactions predominated with Pfizer-BioNTech. After adjustment, female sex, low income, and older age were significant predictors in one or both vaccine groups; comorbidity was not independently associated.
Conclusion: Adverse reactions were predominantly mild and self-limiting across both vaccine platforms. Platform-dependent differences in reactogenicity profile and dose-specific patterns were observed, consistent with the existing post-marketing literature.
Keywords: Community; Data; Health; Patient; Public; Vaccines

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Introduction

The global rollout of COVID-19 vaccines from late 2020 onward drew on a heterogeneous portfolio of platforms, mRNA, adenoviral vector, inactivated whole-virus, and protein-subunit, deployed under differing regulatory pathways across jurisdictions. By late 2021, more than a dozen vaccines were in widespread use worldwide, and international travel gradually resumed under vaccination-status requirements that varied from country to country. [1]

In Australia, four vaccines received provisional approval from the Therapeutic Goods Administration (TGA) for domestic use: Pfizer-BioNTech (Comirnaty), AstraZeneca (Vaxzevria), Moderna (Spikevax), and Janssen. [2] For the purpose of establishing the vaccination status of

international travelers entering the country, the TGA separately "recognized" a further set of vaccines administered overseas, including BBIBP-CorV (Sinopharm), Coronavac (Sinovac), Covaxin (Bharat Biotech), Covishield (Serum Institute of India/AstraZeneca), and, from mid-2022, Sputnik V (Gamaleya). [2] Recognition allowed travelers vaccinated with these products to be treated as fully vaccinated at the border, without implying TGA approval of those vaccines for use in Australia. [3]

This regulatory arrangement created an unusual population of interest: individuals arriving in Australia from a wide range of origin countries, having received their primary COVID-19 vaccination course under different national programs and with different vaccine types. [3] For many recipients of the internationally "recognized" but domestically unapproved vaccines, in particular BBIBP-CorV and Sputnik V, reactogenicity data available in the English-language literature remain comparatively limited and largely derive from studies conducted within the originating countries or regions. By contrast, reactogenicity of the mRNA Pfizer-BioNTech and adenoviral AstraZeneca vaccines has been reported extensively in post-marketing surveillance systems. [4]

Across vaccine platforms, the most frequently reported early adverse events following immunization (AEFIs) are local injection-site reactions and mild systemic symptoms such as fatigue, headache, myalgia, and low-grade fever, with severe reactions remaining rare. [5] Reported reactogenicity varies with host factors, age, sex, comorbidity burden, and previous SARS-CoV-2 infection, as well as with vaccine platform and dose number. [6] Concerns about adverse effects continue to contribute to vaccine hesitancy, including among health-care workers, making transparent post-marketing evidence from diverse populations a continuing public-health priority.

To our knowledge, few studies have directly compared reactogenicity across the mix of mRNA, inactivated, and adenoviral-vector vaccines as experienced by a single, geographically mobile cohort receiving those vaccines under routine (non-trial) conditions in their countries of origin. Inbound international travelers arriving in Australia during 2022 constitute such a cohort, drawn from populations where Sinopharm, Pfizer-BioNTech, and AstraZeneca were each in large-scale use. The aim of this cross-sectional study was therefore to describe the self-reported immediate adverse reactions following initial COVID-19 vaccination among international travelers entering Australia between April and November 2022, and to examine the association between reported reactions and vaccine type, age, sex, comorbidity, and prior COVID-19 infection. Findings from a traveler cohort of this kind are not generalizable to any single national vaccinated population but may contribute to the comparative post-marketing picture across vaccine platforms deployed globally.

Materials and Methods

Study Design and Setting

A cross-sectional online survey was conducted among international travelers arriving in Australia between 20 April and 15 November 2022. The study was approved by the Human Research Ethics Committee of Edith Cowan University (ECU/ERC/22/174) and conducted in accordance with the Declaration of Helsinki. Reporting follows the STROBE statement for cross-sectional studies.

Participants and Eligibility

Eligible participants were English-speaking adults (≥18 years) who had arrived in Australia from overseas during the study period and received at least one dose of a TGA-approved or TGA-recognized COVID-19 vaccine abroad. Individuals vaccinated exclusively within Australia, those who had participated in vaccine clinical trials, and those who declined consent or returned surveys missing both vaccine type and all adverse-effect items were excluded. Traveler status and overseas vaccination were self-reported; no independent verification was performed.

Recruitment and sample size

Participants were recruited via online social media platforms using a snowball sampling strategy through the investigators' professional and community networks. All responses were collected through a self-administered Google Forms questionnaire; no telephone interviews were conducted. Informed consent was obtained electronically on the first page of the form. Assuming a 50% prevalence of any adverse reaction, a 95% confidence level, and a ±2.6% margin of error, the minimum required sample was ~1,420 (Cochran formula). The achieved sample was 1,435. No *a priori* power calculation was performed for subgroup comparisons; these analyses are exploratory.

Survey Instrument

The questionnaire was adapted from a validated instrument used in a UAE-based COVID-19 vaccine reactogenicity study, with contextual modifications for an international traveler cohort (e.g., addition of country of vaccination). [7] It comprised sections on: (1) eligibility screening; (2) demographics (age, sex, income, education, country of origin); (3) comorbidities and allergies; (4) prior SARS-CoV-2 infection and its severity; (5) vaccination details (brand, country, number of doses); and (6) adverse reactions (type, severity, care sought). Content validity was established through independent review by three experts in public health, epidemiology, and family medicine. A five-participant pilot (excluded from the final sample) informed item refinement. Internal consistency of the adverse-reaction items yielded Cronbach's $\alpha = 0.83$.

Classification of Adverse Reactions

Local reactions were defined *a priori* as pain, swelling, redness, induration, warmth, or itching at the injection site. Systemic reactions included fever (≥38.0 °C), headache, fatigue, myalgia, arthralgia, chills, nausea, vomiting, diarrhea, rash distant from the injection site, lymphadenopathy, and anaphylaxis, consistent with Brighton Collaboration AEFI definitions. Severity was self-rated on an 11-point numerical rating scale (0 = no symptom, 10 = worst imaginable) and collapsed *a priori* into *mild* (1–3), *moderate* (4–6), and *severe* (7–10) following the cut-points of Zelman et al. [8] Care-seeking (none / home care / consultation / hospital) was captured separately.

Statistical Analysis

Analyses were performed in IBM SPSS Statistics version 28.0. Categorical variables are presented as frequencies and percentages; continuous variables as means ± SD or medians (IQR) depending on normality (Shapiro–Wilk test). Because AstraZeneca recipients comprised only 12.8% of the sample (n = 184), primary between-vaccine analyses compared Sinopharm (n = 720) and Pfizer-BioNTech (n = 531) only; AstraZeneca data are reported descriptively in a supplementary table.

Associations between demographic/clinical factors and any adverse reaction (yes/no) were tested using Pearson's chi-square (or Fisher's exact test where expected cell counts were <5). Dose-stratified adverse-reaction frequencies were compared using McNemar's test among participants who received both doses.

A two-sided α of 0.05 was used. All *p*-values are reported to three decimal places; values below 0.001 are reported as $p < 0.001$. No correction for multiple comparisons was applied; subgroup results should be interpreted as hypothesis-generating. Missing data were handled by pairwise deletion, with the *n* for each analysis reported in every table.

Age-group Stratification

Participants were stratified into three groups: ≤35, 36–54, and ≥55 years, consistent with published systematic reviews of COVID-19 vaccine safety.

Patient and public involvement

Members of the target population were not involved in the design, conduct, or reporting of this study beyond their role as survey respondents.

Results

Participant characteristics

A total of 1,435 international travelers completed the survey. The majority were female (n = 832; 57.9%), and the largest age group was 36–54 years (n = 646; 45.0%). Approximately one-third of participants (n = 459; 32.0%) reported at least one comorbid condition, and 200 (13.9%) reported a history of COVID-19 infection prior to vaccination.

Vaccination profile

BBIBP-CorV (Sinopharm) was the most commonly received vaccine (n = 720; 50.2%), followed by Pfizer-BioNTech (n = 531; 37.0%) and AstraZeneca (n = 184; 12.8%). This distribution reflects the international origin of the cohort, as BBIBP-CorV was widely deployed in the travelers' countries of vaccination. Most participants had received two or more doses (n = 1,291; 89.9%); 144 (10.0%) had received a single dose. Due to its smaller size, the AstraZeneca subgroup was included in overall descriptive analyses but excluded from between-vaccine comparisons.

Prevalence, severity, and care-seeking

Overall, 947 participants (65.9%) reported at least one adverse reaction following vaccination. The most frequently reported reactions were injection-site pain (47.2%), fatigue or drowsiness (22.8%), headache (18.0%), and myalgia or arthralgia (11.5%). No cases of anaphylaxis or other severe allergic reactions were reported.

When severity was classified using the *a priori* NRS cut-points, the large majority of reported reactions were mild (NRS 1–3: n = 881; 93.0%), followed by moderate (NRS 4–6: n = 60; 6.3%) and severe (NRS 7–10: n = 6; 0.6%). Correspondingly, most participants who experienced adverse reactions required no medical care (n = 702; 74.1%) or managed symptoms with home-based care alone (n = 208; 22.0%). Primary-care consultation was sought by 31 participants (3.3%), and hospitalization was required in only 6 cases (0.6%).

Comparison by Vaccine Type

Pfizer-BioNTech recipients reported a higher mean number of adverse reactions per person than Sinopharm recipients (2.48 ± 2.27 vs 1.72 ± 1.79; $p < 0.001$). The overall likelihood of reporting any adverse reaction was significantly higher among Pfizer-BioNTech recipients (crude OR 1.28; 95% CI 1.05–1.56; $p < 0.01$).

Local reactions were significantly more frequent among Pfizer-BioNTech recipients than Sinopharm recipients (292 [55.0%] vs 288 [40.0%]; $p < 0.001$), while systemic reactions did not differ significantly between groups (244 [45.9%] vs 310 [43.1%]; $p = 0.320$).

Dose-stratified Adverse Reactions

Among Sinopharm recipients, 155 (21.5%) reported adverse reactions after the first dose only, 166 (23.1%) after the second dose only, 109 (15.1%) after both doses, and 290 (40.3%) reported no reaction after either dose. Among Pfizer-BioNTech recipients, 66 (12.4%) reported reactions after the first dose only, 160 (30.1%) after the second dose only, 133 (25.0%) after both doses, and 172 (32.4%) reported no reaction.

First-dose reactions were significantly more common among Sinopharm recipients (21.5% vs 12.4%; OR 1.93; $p < 0.001$), while second-dose reactions were more frequent among Pfizer-BioNTech recipients (30.1% vs 23.1%; OR 1.44; $p < 0.001$). There was no statistically significant difference in local reactions between the first and second doses for either vaccine. However, systemic reactions increased significantly after the second dose of Pfizer-BioNTech compared with the first (McNemar's test, $p < 0.001$), consistent with a dose-dependent reactogenicity pattern for mRNA vaccines.

Bivariate associations with adverse reactions

Table 1 presents the prevalence of any adverse reaction stratified by demographic and clinical factors, separately for Sinopharm and Pfizer-BioNTech recipients, with crude ORs and 95% CIs.

Table 1. Bivariate association of demographic and clinical factors with any adverse reaction, by vaccine type

Variable	S: AE %	S: OR (95% CI)	S: p	P: AE %	P: OR (95% CI)	P: p
Sex (F vs M)	71.4 vs 54.3	1.62 (1.02–2.58)	0.040	47.5 vs 61.2	0.57 (0.40–0.81)	0.001
Age ≥55 vs ≤35	68.8 vs 63.3	1.27 (0.88–1.83)	0.210	69.8 vs 51.3	2.18 (1.45–3.28)	<0.001
Income Low vs high	71.1 vs 64.5	1.35 (1.10–1.92)	0.008	64.8 vs 51.9	1.71 (1.20–2.44)	0.003
Diploma vs PG	71.8 vs 62.7	1.17 (0.82–1.67)	0.122	50.2 vs 51.5	1.28 (0.87–1.88)	0.080
Prior COVID (Y vs N)	66.2 vs 59.8	1.46 (0.98–2.18)	0.060	64.1 vs 63.2	0.74 (0.57–0.96)	0.020
Comorbidity (Y vs N)	70.5 vs 70.2	1.02 (0.71–1.45)	0.920	61.4 vs 62.5	1.05 (0.75–1.46)	0.780

† S = Sinopharm (n = 720); P = Pfizer-BioNTech (n = 531). ORs are crude. Referent categories: male, age ≤35, high income, postgraduate, no prior COVID-19, no comorbidity. F = female; M = male; PG = postgraduate; Y = yes; N = no.

Among Sinopharm recipients, female sex (OR 1.62; $p = 0.040$) and low income (OR 1.35; p

= 0.008) were significantly associated with higher odds of adverse reactions. Prior COVID-19 infection showed a trend toward association (OR 1.46; p = 0.060) but did not reach significance. Comorbidity and educational attainment were not significant.

Among Pfizer-BioNTech recipients, older age (≥55 vs ≤35: OR 2.18; p < 0.001) and low income (OR 1.71; p = 0.003) were significant predictors. Notably, female sex was associated with lower odds of adverse reactions in this group (OR 0.57; p = 0.001), an effect opposite to the Sinopharm group. Prior COVID-19 infection was associated with marginally lower odds among Pfizer-BioNTech recipients (OR 0.74; p = 0.020). Comorbidity was not significantly associated with adverse reactions in either group.

Multivariable Analysis

Binary logistic regression models adjusting for sex, age group, income, education, prior COVID-19 infection, and comorbidity were fitted separately for each vaccine group. Hosmer–Lemeshow goodness-of-fit tests were non-significant for both models, indicating adequate fit. All variance inflation factors were below 2.0, confirming no multicollinearity. Adjusted ORs are presented in Table 2.

Table 2. Multivariable logistic regression: adjusted odds ratios for any adverse reaction, by vaccine type

Variable	S: aOR (95% CI)	S: p	P: aOR (95% CI)	P: p
Female sex	1.58 (1.05–2.40)	0.030	0.62 (0.45–0.86)	0.004
Age ≥55 years	1.20 (0.82–1.76)	0.300	2.05 (1.35–3.11)	<0.001
Low income	1.32 (1.01–1.89)	0.040	1.64 (1.18–2.28)	0.003
Prior COVID-19 infection	1.40 (0.95–2.07)	0.080	0.76 (0.58–0.98)	0.030
≥1 comorbidity	1.02 (0.71–1.45)	0.920	1.05 (0.75–1.46)	0.780

† S = Sinopharm; P = Pfizer-BioNTech. aOR = adjusted odds ratio. Referent categories: male, age ≤35, high income, no prior COVID-19, no comorbidity. Education was non-significant in bivariate analysis and excluded from the final model.

After adjustment, the principal findings from bivariate analysis were largely preserved. Among Sinopharm recipients, female sex (aOR 1.58; p = 0.030) and low income (aOR 1.32; p = 0.040) remained significant predictors. Among Pfizer-BioNTech recipients, older age (aOR 2.05; p < 0.001), low income (aOR 1.64; p = 0.003), and female sex (aOR 0.62; p = 0.004) remained independently associated with adverse reactions. Prior COVID-19 infection retained a modest protective association (aOR 0.76; p = 0.030) among Pfizer-BioNTech recipients. Comorbidity was not independently associated with adverse reactions in either vaccine group.

Discussion

This cross-sectional study examined self-reported adverse reactions to COVID-19 vaccines among 1,435 international travelers arriving in Australia in 2022, a cohort that, by virtue of its geographic mobility, received vaccines under multiple national programs and thus permits direct comparison of reactogenicity across platforms within a single survey. Approximately two-thirds (65.9%) of participants reported at least one adverse reaction, of which the overwhelming majority (93.0%) were rated as mild on a validated numerical rating scale. Pain at the injection site was the single most common complaint, followed by fatigue, headache, and myalgia. No participant reported anaphylaxis or other severe allergic reactions.

These findings are broadly consistent with the post-marketing surveillance literature across vaccine platforms. Injection-site pain, fatigue, and headache were also the most commonly reported symptoms in the UAE observational study from which our survey instrument was adapted, in systematic reviews of COVID-19 vaccine trial data, and in studies from Japan and Saudi Arabia focusing on Pfizer-BioNTech and Sinopharm recipients specifically. [7, 9, 10] Certain uncommon side effects documented in Middle Eastern populations, such as depression, lymphadenopathy, metallic taste, and constipation were not observed in our cohort, possibly reflecting differences in sample composition, recall period, or survey item specificity.

The principal finding of the present study was that Pfizer-BioNTech recipients reported significantly more adverse reactions per person (2.48 ± 2.27 vs 1.72 ± 1.79) and had higher adjusted

odds of reporting any reaction than Sinopharm recipients. This aligns with earlier head-to-head comparisons of mRNA and inactivated vaccines conducted in Jordan, and the UAE. [11, 12] The mechanistic explanation is plausible: mRNA vaccines elicit a robust innate immune response, including production of type I interferons and pro-inflammatory cytokines, that is thought to underlie both their strong immunogenicity and their higher reactogenicity profile compared with inactivated whole-virus vaccines, which present antigen in a less immunostimulatory context.

We also observed a dose-dependent divergence in reactogenicity patterns between the two vaccines. First-dose adverse reactions were more frequent among Sinopharm recipients, whereas second-dose reactions predominated in the Pfizer-BioNTech group. This mirrors findings from United Kingdom-based surveillance data and from a Japanese healthcare-worker cohort, in which systemic reactions, particularly fatigue and fever, increased markedly after the second dose of mRNA vaccines. [13] The pattern is consistent with immune priming: the first mRNA dose generates a strong primary response, and the second dose triggers a more vigorous anamnestic reaction. By contrast, the relatively higher first-dose reactogenicity observed with the inactivated Sinopharm vaccine may reflect an adjuvant-mediated inflammatory response to the whole-virus preparation that partially attenuates with repeated exposure.

An unexpected finding was the opposing direction of the sex effect between vaccine groups. Among Sinopharm recipients, females had higher odds of adverse reactions (aOR 1.58), whereas among Pfizer-BioNTech recipients, males had higher odds (aOR for females: 0.62). The female predominance for Sinopharm-related reactions is consistent with the broader literature, which has repeatedly documented higher vaccine reactogenicity in women, attributed in part to hormonal modulation of innate and adaptive immune responses. [14, 15] The reversal in the Pfizer-BioNTech group is less readily explained. One possibility is confounding by country of origin or age structure within the Pfizer subgroup, which differed from the Sinopharm subgroup owing to the different geographic deployment of these vaccines. This discrepancy warrants further investigation in larger, more geographically stratified cohorts.

Older age (≥55 years) was a significant predictor of adverse reactions among Pfizer-BioNTech recipients (aOR 2.05) but not among Sinopharm recipients. This finding diverges from several studies reporting higher reactogenicity in younger adults, particularly with mRNA vaccines. [16] However, it should be interpreted with caution, as the ≥55 subgroup was the smallest (n = 74 for Pfizer), and the confidence intervals were wide. Low household income was independently associated with higher odds of adverse reactions in both vaccine groups after adjustment. While socioeconomic status is not a direct biological modifier of reactogenicity, lower income may correlate with reduced health literacy, more physically demanding occupations (amplifying perceived impact of symptoms), or differences in reporting behavior.

Comorbidity was not significantly associated with adverse reactions in either vaccine group after adjustment, consistent with the observation that the study captured primarily mild, self-limiting AEFIs rather than the serious adverse events more closely linked to underlying disease.[13] Among Pfizer-BioNTech recipients, prior COVID-19 infection was associated with marginally *lower* odds of adverse reactions (aOR 0.76; p = 0.030). This direction of effect, while counterintuitive, has precedent: researchers have shown that individuals with prior infection mount a strong anamnestic response to a single mRNA dose, and some surveillance data suggest that the *subjective severity* of post-vaccination symptoms may not scale linearly with immune activation. [17] Alternatively, prior COVID survivors may have recalibrated their symptom-severity expectations, rating similar symptoms lower on the NRS than vaccine-naïve individuals. This finding merits caution given the exploratory nature of the subgroup analysis.

This study has several strengths. First, it offers a direct within-cohort comparison of reactogenicity across mRNA and inactivated vaccine platforms under real-world, non-trial conditions, a comparison that single-country studies typically cannot provide, because most national programs deployed a limited set of vaccines. Second, the sample size (n = 1,435) was prospectively determined and achieved adequate precision for estimating overall prevalence. Third, severity was captured on a validated NRS with *a priori* cut-points, rather than relying on undefined severity labels, enabling reproducible categorization.

Several limitations should be considered when interpreting these results. First, the cross-sectional, self-report design is subject to recall bias; participants were asked about adverse reactions that occurred at varying intervals after vaccination, and the accuracy of retrospective symptom reporting may decline over time. Second, the snowball

sampling strategy via social media limits the generalizability of the findings. The sample is not representative of all international travelers to Australia, nor of any single national vaccinated population; it is self-selected, English-speaking, and likely over-represents individuals with access to social media and motivation to share their vaccination experience. Third, vaccination status and vaccine brand were self-reported and were not verified against official immunization records or vaccination certificates. Fourth, the questionnaire did not collect data on the interval between vaccination and survey completion, which precludes assessment of the effect of recall interval on reporting. Fifth, the AstraZeneca subgroup was too small for meaningful between-vaccine comparison, limiting analysis to the two largest groups. Sixth, the subgroup analyses were not pre-powered and should be viewed as hypothesis-generating. Finally, the study captured only self-reported symptoms within the immediate post-vaccination window; it was not designed to detect rare or delayed adverse events, nor to assess vaccine efficacy or antibody response.

Despite these limitations, the findings carry practical implications. The confirmation that the overwhelming majority of adverse reactions across both vaccine platforms were mild and self-limiting adds to the body of reassurance that can be communicated to vaccine-hesitant populations. At the same time, the platform-dependent differences in reactogenicity profile, including the dose-specific pattern and the higher mean symptom count with mRNA vaccines, underscore the value of platform-stratified post-marketing data, particularly for vaccines deployed predominantly in low- and middle-income countries where English-language reactogenicity data remain sparse. Future studies should ideally employ prospective, app-based or diary-based symptom capture to minimise recall bias, incorporate serological endpoints to link reactogenicity to immunogenicity, and include sufficiently large and geographically stratified samples to permit robust subgroup analysis across vaccine platforms.

Conclusion

In this survey of 1,435 international travelers entering Australia in 2022, approximately two-thirds reported at least one adverse reaction following COVID-19 vaccination, of which 93% were mild and rarely required medical care. Pfizer-BioNTech recipients reported a higher frequency and mean number of adverse reactions than Sinopharm recipients, with a dose-dependent pattern characterized by more first-dose reactions in Sinopharm and more second-dose reactions in Pfizer-BioNTech. Female sex, low income, and older age were associated with higher odds of adverse reactions in one or both vaccine groups after adjustment, while comorbidity was not independently associated. These data indicate that self-reported reactogenicity across the two most widely received vaccine platforms in this traveler cohort was largely consistent with the existing post-marketing literature, and predominantly comprised mild, self-limiting symptoms. These findings may contribute to evidence-based risk communication for diverse, globally mobile populations.

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Author Contribution

FS conceived the idea, collected data, and wrote the initial manuscript. RK collected data, analyzed the data, validated the results, and proofread the finalized manuscript.

Data Availability Statement

All relevant data are within the manuscript. Additional data supporting this study are available from the corresponding author upon reasonable request.

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Conflict of Interest

The authors declare no conflicts of interest.

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