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Incidence rates of bullous pemphigoid, herpes zoster and urticaria following the start of the COVID-19 vaccination programme in the UK: a population-based cohort study

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Abstract

Background Several population-based studies have reported an increased risk of serious skin conditions following COVID-19 vaccinations, but their population samples were not representative. Accurately estimating these risks is important for understanding vaccine hesitancy and improving clinical practice.

Objectives To compare the incidence rates (IRs) of bullous pemphigoid (BP), herpes zoster (HZ) and urticaria before and after the UK's COVID-19 vaccination programme started.

Methods We conducted a population-based cohort study using electronic healthcare records from the Clinical Practice Research Datalink (1 January 2019–31 May 2023). We estimated monthly IRs (cases/100 000 person-years) for BP, HZ and urticaria. Using interrupted time series analysis, we compared changes in the IR slopes before and after the vaccine programme started (intervention). Sensitivity analyses were adjusted for COVID-19 lockdowns and total general practitioner (GP) appointments.

Results In total, 16 156 639 adults (aged ≥ 18 years) registered at a general practice between 1 January 2019 and 31 May 2023 (BP, $n=3506$; HZ, $n=129\,668$; urticaria, $n=63\,320$). The BP IR (cases/100 000 person-years) did not change postintervention vs. the preintervention period. We did not detect pre- and postintervention slopes. Sensitivity analysis results were similar. Preintervention, there was a downward slope for the HZ IR [–4.44, 95% confidence interval (CI) –5.54 to –3.35; $P<0.005$]. The HZ IR increased postintervention vs. the preintervention period (5.15, 95% CI 3.43–6.88; $P<0.005$). Despite the increase in the HZ IR, we found no evidence of a postintervention slope. Sensitivity analysis results were similar. Preintervention, there was a downward slope for the urticaria IR (–3.42, 95% CI –4.13 to –2.70; $P<0.005$). The urticaria IR increased postintervention vs. the preintervention period (4.40, 95% CI 3.27–5.53; $P<0.005$), resulting in an upward slope (0.98, 95% CI 0.43–1.52; $P<0.005$). However, after accounting for lockdowns or GP appointments, the upward postintervention slope was no longer apparent.

Conclusions While the BP IR did not change following the COVID-19 vaccine programme in the UK, we detected increased IRs for HZ and urticaria. However, these increases were modest, and, for many, the benefits of vaccination will probably outweigh the potential risks. Future research should use individual patient-level studies (e.g. self-controlled case series) to determine whether the increases in HZ and urticaria IRs are driven by COVID-19 vaccines.

Lay summary

Following the start of COVID-19 immunization programmes worldwide, serious skin reactions were reported after getting the COVID-19 vaccines. These included bullous pemphigoid ('BP' for short), shingles and hives. BP is a rare autoimmune skin disease that mainly affects older people. About 8 in 100,000 people a year in the UK develop BP. The cause of BP is unknown. Symptoms often start with very itchy skin and a rash. Over time, these develop into painful blisters and open sores. Shingles typically results in a painful rash over the chest and abdomen. The condition is most common in people older than 80 years of age. About 1,100 in 100,000 people a year in the UK develop shingles. Hives presents as a rash with raised bumps. Around 8% to 10% of the UK's population will get hives at least once in their lives, mostly between the ages of 20 and 40 years old.

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Previous studies found links between COVID-19 vaccines and BP, shingles and hives. However, the people included in the studies were not representative of the UK's population. Accurate estimates of the risks of developing these diseases with a sample representative of the UK are important. More accurate information will help healthcare professionals and inform those who are hesitant about vaccines. In this study, we used information gathered by more than 2,000 general practices in the UK to compare changes in how often BP, shingles and hives were seen before and after the COVID-19 vaccination programme. We found that the number of cases of BP did not change after the vaccination programme. Cases of shingles and hives increased. However, the increases were not large. The benefits of vaccination will probably outweigh the potential risk of developing hives and shingles for many people.

Future research should explore whether the increases in BP, shingles and hives that we found are driven by the COVID-19 vaccines or other reasons.

What is already known about this topic?

- The rapid development and approval of COVID-19 vaccines caused worldwide vaccine hesitancy due to concerns about their safety.
- Few population-based studies have shown an increased risk of serious skin conditions following COVID-19 vaccines, but their cohorts were not representative of the UK population.

What does this study add?

- There is no evidence that the incidence rate (IR) of bullous pemphigoid has changed following the start of the COVID-19 vaccine programme.
- The IRs for herpes zoster and urticaria have increased vs. the prevaccination period.
- Increases in the IRs for herpes zoster and urticaria are modest.
- The next step is to use individual patient-level studies (e.g. self-controlled case series) to determine whether the increases in bullous pemphigoid, herpes zoster and urticaria are driven by COVID-19 vaccines.

The UK was the first country to approve the use of COVID-19 vaccines and start immunizations.[1] Rapid vaccine development prevented approximately 14 million COVID-19-related deaths worldwide in the first year of the UK's immunization programme.[2] However, there is substantial mistrust of vaccines, which remains a barrier to population immunity.[3,4] Some concerns raised about vaccine safety included cutaneous reactions triggered by immune system stimulation.[3,5–12] Although rare, such reactions can be serious.[12] Understanding which adverse cutaneous reactions will probably present after COVID-19 immunization is crucial to inform clinical practice and improve public confidence.

Several studies have reported adverse cutaneous reactions after COVID-19 vaccines, including bullous pemphigoid (BP), herpes zoster (HZ) and urticaria.[7–11] BP is a serious autoimmune blistering disease of older people with a threefold higher mortality than found in the general population.[13,14] The mechanism behind vaccine-induced BP is unknown. Several vaccines, including influenza, swine flu, HZ virus and others, have been associated with BP.[15]

HZ manifests as a painful blistering rash, negatively affecting patients' quality of life.[16,17] The immunological response behind HZ is caused by varicella zoster virus (VZV) reactivation during reduced immunity.[16] Two processes were proposed behind VZV reactivation following COVID-19 vaccines: the innate or cell-mediated immune defence failure and temporal incapability of $CD8^+$ T cells of controlling the virus when they significantly expand in response to the vaccine.[18–20]

Urticaria primarily affects people aged < 40 years and 20% of the population during their lifetime; it was also seen following COVID-19 vaccines.[21–23] The reaction presents with localized or more generalized raised, itchy wheals, with individual lesions lasting < 24 h. Urticaria can be acute or chronic, with immediate or delayed onset.[8,10] Immunological responses resulting in suppressed histamine-releasing autoantibody or increased anti-FcεRIα autoantibody production were proposed mechanisms of vaccine-induced chronic spontaneous urticaria (CSU).[24]

Given various reports of the highlighted conditions (BP, HZ and urticaria) following COVID-19 vaccination, painful symptoms and variable prevalence in different age groups, it is important to investigate the nationwide incidence rates (IRs) following the UK's COVID-19 vaccination programme. If the vaccination programme was not associated with increased IRs of the examined conditions, this information may reassure patients about vaccine safety. Should there be an association, the findings will help patients make informed decisions about vaccinating and enable clinicians to recognize these conditions earlier.

To our knowledge, no large population-based studies have used samples representative of their target general populations to assess whether the COVID-19 vaccines are associated with BP, HZ and urticaria. To address this knowledge gap, we conducted a population-based cohort study using routinely collected electronic healthcare records representative of the UK population.

Materials and methods

Study design

We conducted a population-based cohort study using interrupted time series analysis of the monthly IRs per 100 000 person-years of BP, HZ and urticaria.

Data sources

We used Clinical Practice Research Datalink (CPRD) data from the GOLD and Aurum databases. The CPRD contains electronic healthcare records from > 2200 general practices and is representative of the UK population.[25,26] We included monthly vaccination uptake and general practitioner (GP) appointment data from the NHS Digital platform to estimate (i) the time to immunize most of the population and (ii) healthcare availability during the COVID-19 pandemic.[27]

Study population

We selected people aged ≥ 18 years registered with a general practice between 1 January 2019 and 31 May 2023. Cohort entry was determined by the latest date selected from the registration date, up-to-standard date (GOLD), eighteenth birthday and 1 January 2019. Patients left the cohort at the earliest selected from the registration end date, last collection date and date of death. Patients had at least 1 year of follow-up, to minimize the inclusion of prevalent BP, HZ and urticaria cases.[28] We used the whole study population and stratified by age group, to account for differences in vaccine rollout by age.[13,22,29] For BP and HZ, the age groups (years) were: < 60, 60–69, 70–79, 80–90 and > 90. For urticaria, the age groups (years) were: 18–29, 30–39, 40–49, 50–59 and ≥ 60 (based on the peak incidence of CSU seen in those aged 20–40 years).[22]

Cases

We used Read codes to select cases of BP, HZ and urticaria (Tables S1–S6; see Supporting Information). The earliest diagnosis date (index date) was identified.

Incidence rates per age group

We accounted for age as a time-varying covariate when calculating the monthly IR per age group. Age was updated each January (due to scarce birth month data). Each year, cases and patients from the CPRD denominator data were assigned to respective age groups, followed by monthly IR calculations.

Main analysis

Interrupted time series (ITS) analysis was conducted using time-lagged linear regression models to evaluate the impact of the UK vaccine programme (intervention). We set the intervention to January 2021, the first whole month since the programme started. Models were designed a priori,[30] and estimated the (i) preintervention slope and (ii) change in the postintervention slope vs. the preintervention one. The postintervention slope was a linear combination of (i) and (ii).[31]

We assumed no sudden change in the monthly IRs postintervention due to a vaccine rollout. Moreover, booster dose uptake could affect postintervention IRs. To account for these factors, we performed an age-stratified analysis. We introduced a rollout lag for the change in the postintervention slope for each condition by counting the months each age group took to achieve 80% of their maximum first-dose uptake rates (Figure S1, Table S7; see Supporting Information). The whole cohort analysis averaged the rollout lag from all age groups. When analysing the change in BP IRs, we accounted for an additional 3-month diagnostic delay lag for the preintervention slope and the change in the postintervention slope to reflect challenges in recognizing this condition and confirming its diagnosis in primary care (Table S7).[32] Model details can be found in Appendix S1 (see Supporting Information).

Our models assumed observation independence, which required low autocorrelation of residuals (correlation between subsequent observations) if our a priori model assumptions were correct.[30] We checked autocorrelation plots of the model residuals from the non-age-stratified analyses for patterns suggesting insufficient model assumptions to describe changes in IRs following our intervention. We considered a P-value < 0.005 to be statistically significant following Bonferroni correction, based on the age-stratified analysis, which estimated the preintervention slope and the change in the postintervention slope in each of the five age groups [i.e. 0.05/(2 × 5)]. All model variants are described in Appendix S1.

Sensitivity analyses

To address unencoded diagnoses during the COVID-19 lockdowns, we conducted sensitivity analyses to assess the impact of public health policy on IRs. The first analysis was adjusted for a lockdown indicator variable in all models, accounting for the UK government's pandemic response in April–June 2020 and January–July 2021.[33] We timed the first national lockdown in April because it was the first entire month affected by a lockdown. The second analysis was adjusted for total GP appointments, evaluating whether primary care availability and postpandemic backlogs affected IR estimates. Appointment data were available for NHS England but not Scotland, Wales or Northern Ireland. Therefore, we repeated the main and sensitivity analyses restricted to English practices, to validate the sensitivity analyses. All analyses were conducted with R version 4.3.1 (R Foundation for Statistical Computing, Vienna, Austria).

Results

Study population

The study population comprised 16 156 639 people. There were 3506, 129 668 and 63 320 incident cases of BP, HZ and urticaria, respectively (Figure 1). The median age of patients with BP, HZ and urticaria was 80 [interquartile range (IQR) 71–86], 61 (IQR 47–72) and 45 (IQR 32–61), respectively. Fifty per cent (n = 1756/3506) of patients with BP, 60% (n = 78 431/129 668) of those with HZ and 67% (n = 42 469/63 320) of those with urticaria were women.

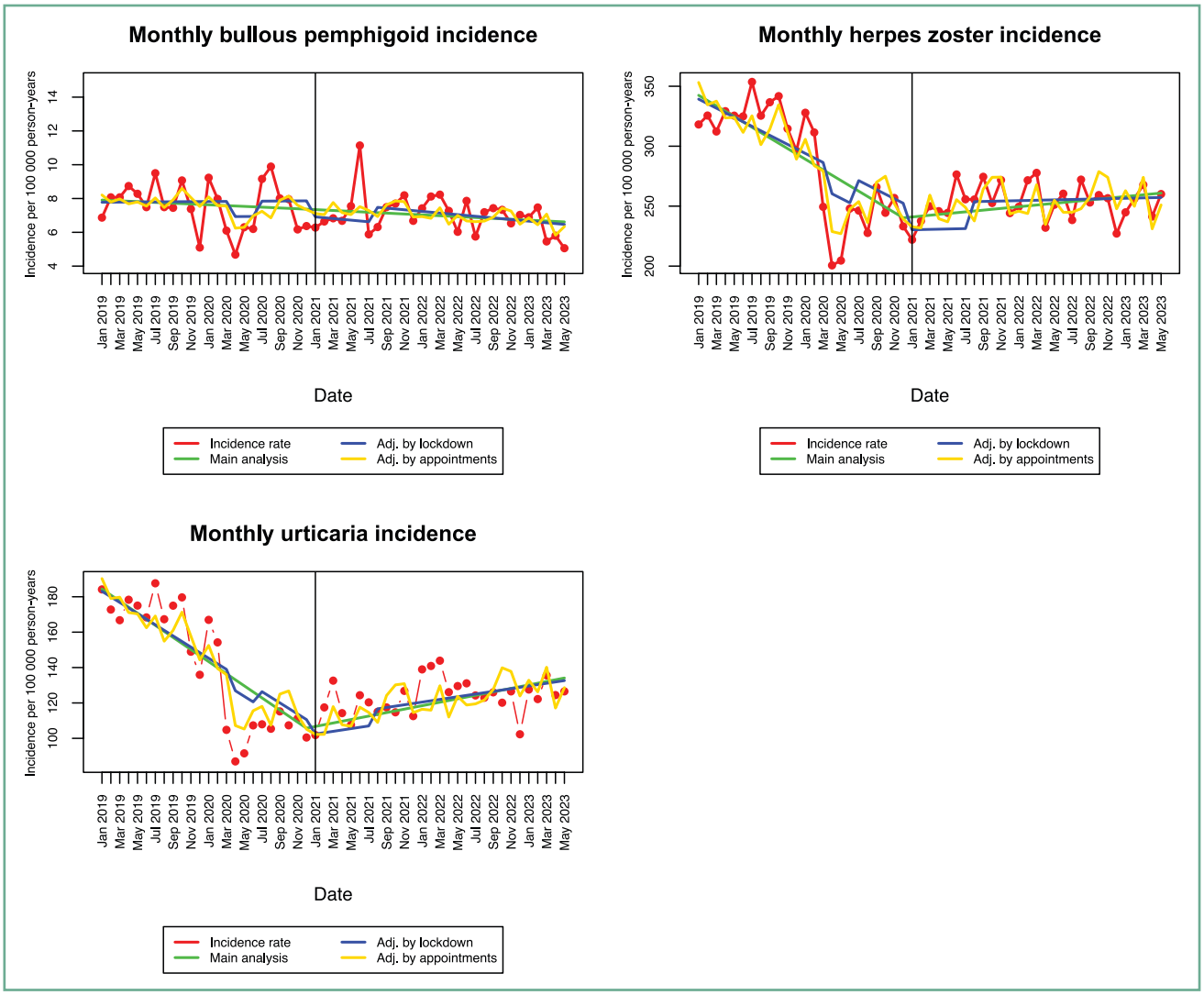

Figure 1 Model fits of interrupted time series analyses of the whole study population and the incidence rate (IR) for each condition.

Bullous pemphigoid

Main analysis

We found no evidence of a change in the postintervention slope of the BP IR [0.00, 95% confidence interval (CI) −0.09 to 0.09; $P=0.96$] vs. its preintervention slope (−0.02, 95% CI −0.08 to 0.03; $P=0.42$) (Figures 1, 2). We also found no evidence of a postintervention slope (−0.03, 95% CI −0.07 to 0.02; $P=0.24$). In the age-stratified analysis, we found a downward postintervention slope in the 60–69 years age group (−0.13, 95% CI −0.22 to −0.05; $P<0.005$).

Sensitivity analyses

Adjusted for lockdown. When we adjusted for the occurrence of the national lockdowns (April–June 2020 and January–July 2021) in our analysis, the results for BP remained similar (Figure 3).

Adjusted for general practitioner appointments. When we adjusted for the total monthly GP appointments in our analysis, the results for BP remained similar (Figure 4).

Herpes zoster

Main analysis

We estimated that the HZ IR had a downward preintervention slope (−4.44, 95% CI −5.54 to −3.35; $P<0.005$) (Figures 1, 2). The change in the postintervention slope showed an increase in the HZ IR (5.15, 95% CI 3.43–6.88; $P<0.005$) vs. preintervention. However, we found no evidence of a specific postintervention slope (0.71, 95% CI −0.12 to 1.54; $P=0.09$).

Time series analysis of the age-stratified HZ IR gave similar results (Figure 2). However, we found that the preintervention slope in the 60–69 years, 70–79 years and 80–89 years age groups showed a greater decrease in the average HZ IR per month than in the group aged 18–59 years (Figure 2). Conversely, we found that in the 60–69 years and 70–79 years age groups, the change in the postintervention slope vs. the preintervention slope showed a greater increase in the HZ IR than in those aged 18–59 years (Figure 2).

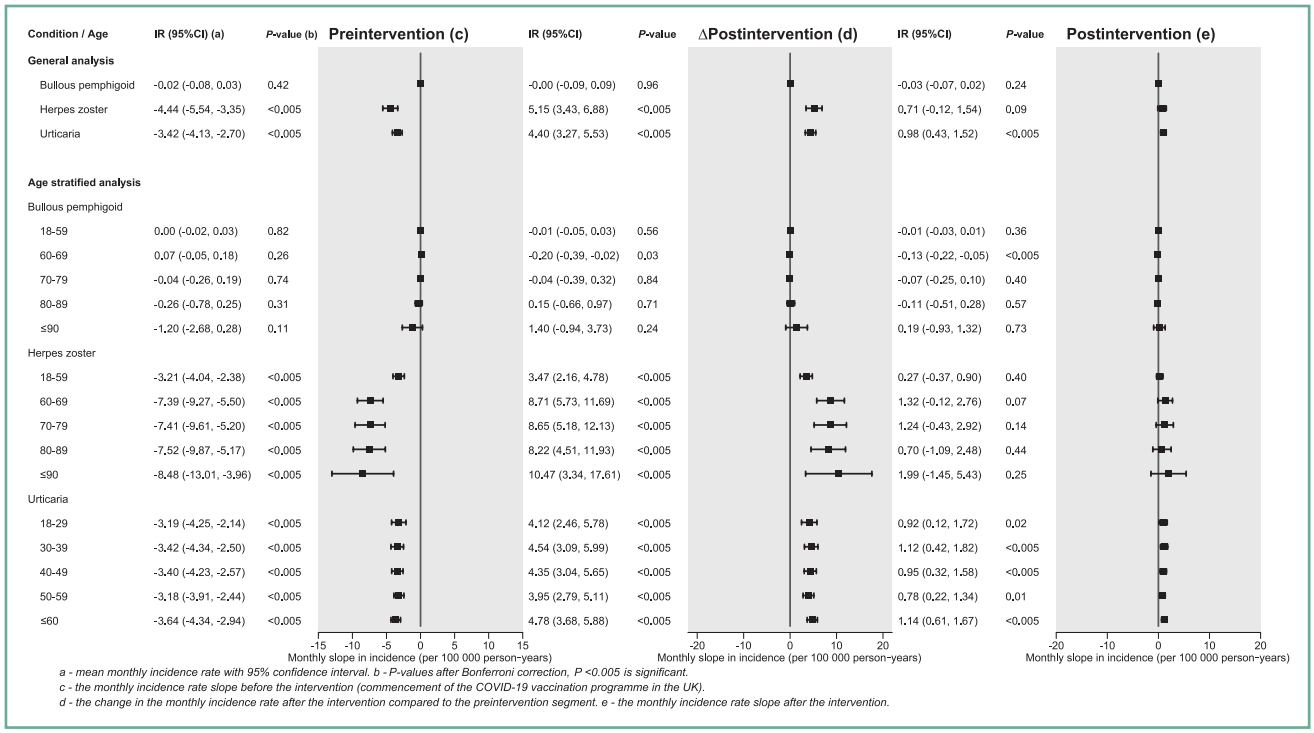

Figure 2 Monthly incidence rate (IR) slopes before and after the start of the COVID-19 vaccination programme in the UK (intervention). The main and age-stratified analyses for the entire study population. CI, confidence interval.

Sensitivity analyses

Adjusted for lockdown. The HZ results in the analysis not stratified by age remained similar after adjusting for the occurrence of the national lockdowns (April–June 2020 and January–July 2021; Figure 3). However, we did not find age-related differences in the change of the HZ IR postintervention slope vs. its preintervention slope. We also found no evidence of change in the postintervention slope vs. the preintervention slope for the 80–80 years and ≥90 years age groups.

Adjusted for general practitioner appointments. The HZ results in the analysis not stratified by age remained similar after adjusting for the total monthly GP appointments (Figure 4). In the age-stratified analysis, we found no evidence of change in the postintervention slope vs. the preintervention slope for people aged ≥90 years.

Urticaria

Main analysis

The preintervention slope showed an average decrease in the urticaria IR (–3.42, 95% CI –4.13 to –2.70; $P<0.005$) (Figures 1, 2). Compared with the preintervention slope, the postintervention slope showed an increase in the urticaria IR (4.40, 95% CI 3.27–5.53; $P<0.005$). We also detected an upward postintervention slope of the urticaria IR (0.98, 95% CI 0.43–1.52; $P<0.005$).

In the age-stratified analysis, the preintervention slope and the change in the postintervention slope were similar to the main analysis across the age groups (Figure 1). We found a postintervention slope only for the groups aged 30–39 years, 40–49 years and ≥60 years (Figure 2).

Sensitivity analyses

Adjusted for lockdown. After adjusting for the occurrence of the national lockdown (Figure 3), we found no evidence of a postintervention slope for the urticaria IR (0.76, 95% CI 0.14–1.38; $P=0.02$). In the age-stratified analysis, the preintervention slope and the change in the postintervention slope vs. the preintervention slope remained similar to the main analysis. However, we only found evidence of an upward postintervention slope for the urticaria IR in the group aged ≥60 years (0.91, 95% CI 0.31–1.52; $P<0.005$).

Adjusted for general practitioner appointments. After adjusting for the total monthly GP appointments, the results were similar to when we adjusted for the occurrence of national lockdowns (Figure 4). However, in age-stratified analysis, we found no evidence of a postintervention slope in the group aged ≥60 years when we adjusted for the total monthly GP appointments.

Study population restricted to English practices

After adjusting for the total monthly GP appointments and restricting to English practices, the results were similar to estimates for the entire study population (Figure S2; see Supporting Information).

Autocorrelation function plots

The models exhibited low autocorrelation with no patterns crossing the 95% confidence bands (Figures S3–S5; see Supporting Information). Therefore, it is unlikely that we omitted potentially important covariates.

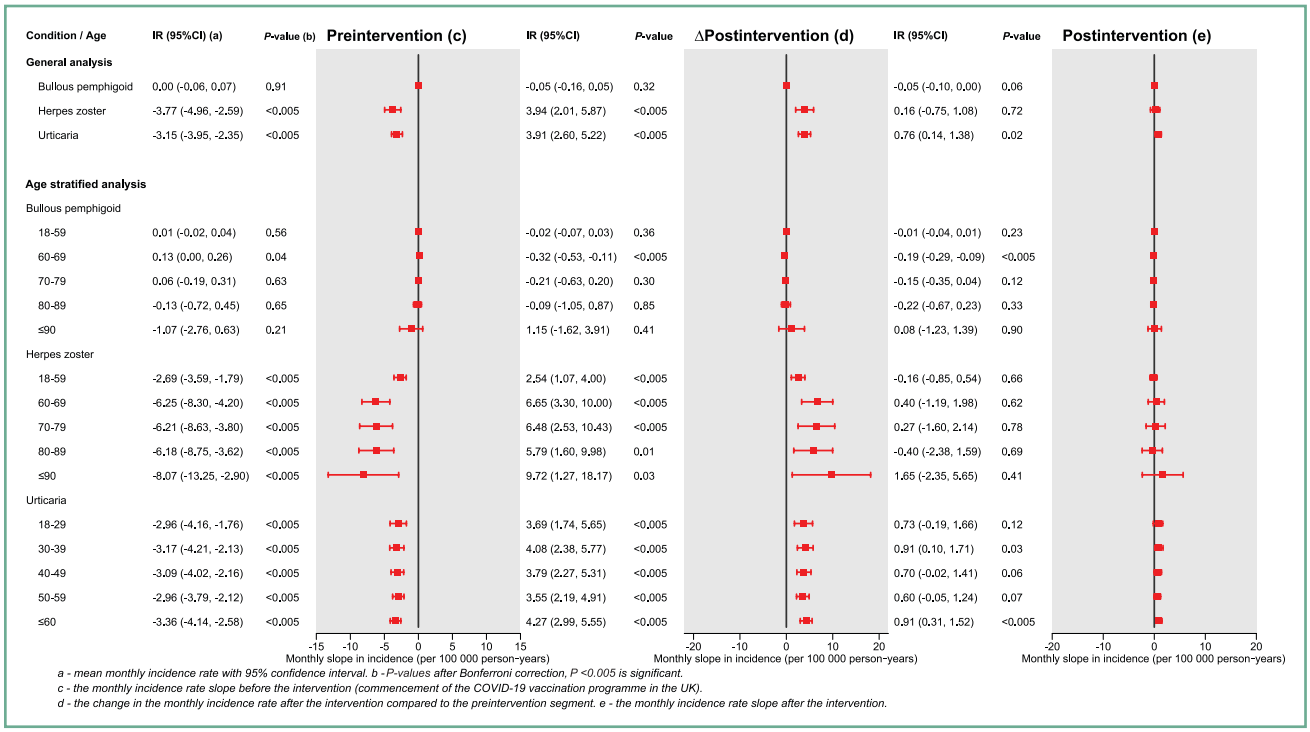

Figure 3 Monthly incidence rate (IR) slopes before and after the start of the COVID-19 vaccination programme in the UK (intervention) after adjusting for the timing of the COVID-19 national lockdown. The main and age-stratified analyses for the entire study population. CI, confidence interval.

Discussion

Following the onset of the COVID-19 vaccination programme in the UK, there is no evidence that the IR of BP increased. However, the IRs of HZ and urticaria increased compared with their preintervention IRs. These changes could be explained by vaccinations or coincident factors that require further investigation in patient-level study designs.

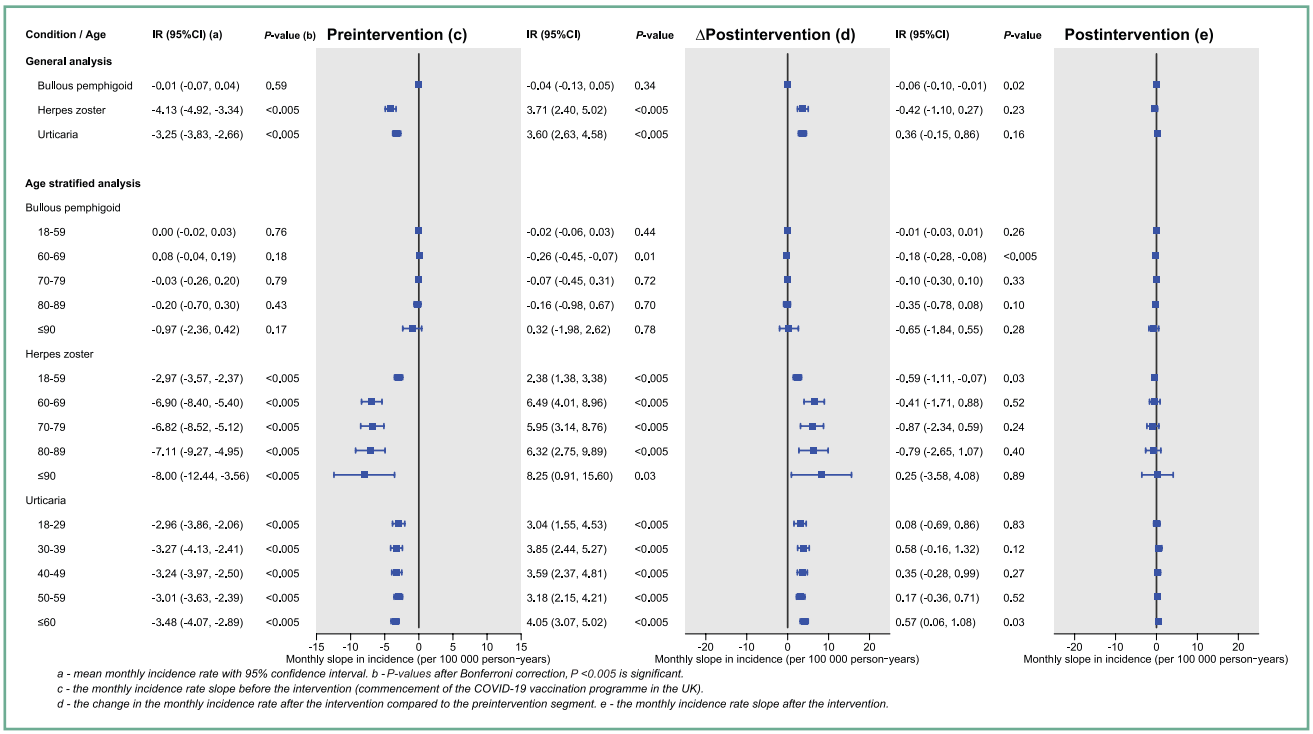

Figure 4 Monthly incidence rate (IR) slopes before and after the start of the COVID-19 vaccination programme in the UK (intervention) after adjusting for the total monthly general practitioner appointments (NHS England data). The main and age-stratified analyses. CI, confidence interval.

Furthermore, the increase in the IRs for HZ and urticaria following COVID-19 vaccination were modest compared with our cohort's overall reported IRs.

Preintervention, the slopes showed that the IRs for HZ and urticaria declined. Our analysis detected a postintervention slope only for the IR for urticaria, with a slight increase in cases each month. The slope did not remain statistically significant after adjusting for national lockdowns and total GP appointments separately. However, sensitivity analyses detected increases in the IRs for HZ and urticaria, similar to the main analysis. Therefore, we cannot reject the possibility that the IRs for HZ and urticaria changed following the vaccination programme.

The recording of cases of BP was probably unaffected by the national COVID-19 lockdowns. Patients with BP usually present with severe blistering and widespread itching, which prompts referral to and diagnosis by a dermatologist. Under-reporting of HZ and urticaria could be attributed to seeking pharmacy treatment during the national lockdowns if patients' symptoms were mild.[34,35]

Previous population-based cohort studies have examined relative risk rather than the absolute incidence changes of these conditions over time. The cohort study by Birabaharan *et al.* found no association between COVID-19 vaccines and BP [risk ratio (RR) 0.77, 95% CI 0.37–1.57].[36] Our results confirm these findings: the IR of BP did not change after the vaccine programme started.

For HZ, our findings are consistent with those of previous cohort studies that reported an increased risk of HZ following COVID-19 vaccines (RR 1.802, 95% CI 1.680–1.932), and a case–control study by Wan *et al.*, where increased HZ risk after COVID-19 vaccination was also found.[37–39] Conversely, Akpandak *et al.* found no association between COVID-19 vaccines and HZ (incidence rate ratio 0.91, 95% CI 0.82–1.01).[40] However, their estimates used an insurance claims database covering insured populations and healthcare activities attracting payment, as opposed to the CPRD, which contains routinely collected healthcare data for the whole population and covers all conditions.[40,41] Case/no-case studies using self-reported pharmacovigilance data, such as that of Préta *et al.*,[42] found an increased risk of HZ after the Pfizer–BioNTech and Moderna vaccines [reporting odds ratio (ROR) 1.9, 95% CI 1.8–2.1], while Gringeri *et al.* reported an increased risk following the Pfizer–BioNTech vaccine (ROR 1.49, 95% CI 1.42–1.57).[43] The reliability of self-reporting systems is limited due to under-reporting bias and missing data.[44,45]

Regarding urticaria, our findings are consistent with previous studies which showed that the IR of urticaria increased after the start of COVID-19 vaccination programme. A Swiss prospective cohort study showed a high IR of CSU after COVID-19 vaccination [IR (per 100 000) 19.3, 95% CI 17.8–20.9].[46] A case–control study by Magen *et al.* reported an increased risk of CSU after the Pfizer–BioNTech vaccine (odds ratio 5.54. 95% CI 2.36–13.02).[24]

The main strengths of our study were its cohort design and the large study sample, representative of the UK general population. The hypotheses about changes in the IRs of the examined conditions following the intervention were formulated a priori with respect to the ITS analysis. Our models incorporated vaccination rollouts and diagnostic delay in BP. We also performed sensitivity analyses, assessing whether national lockdowns and GP appointment availability affected the IRs. The analyses produced similar results, strengthening the validity of the findings.

The completeness and accuracy of CPRD records might vary due to the nature of routinely collected data, which depends on manual input, diagnostic coding variations between GPs and patients not seeing their GP.[26] The latter could have been more common during the first national lockdown. Patients with HZ and urticaria may have avoided GP visits due to the public health policy in place at the time. The effectiveness and quality of remote consultations may have also affected the accuracy of recorded diagnoses of skin conditions. Moreover, GPs' diagnostic confidence could have been affected, making diagnoses recorded in free text unavailable to researchers. These factors may have affected the robustness of the main analysis and may explain why the IRs decreased before vaccinations. We also did not adjust for the timing of COVID-19 vaccine types, after which the risk of the investigated conditions might differ. Furthermore, we did not adjust for the timing of vaccination campaigns to account for the possible T-cell exhaustion effect on the risk of examined conditions following repeated vaccinations.[47]

Other COVID-19-related factors may also explain the changes in the IRs following the vaccination programme. For example, the disruption of routine vaccinations during the COVID-19 pandemic may have affected the IR of HZ following the start of the vaccination programme.[48] Notably, we did not account for HZ vaccinations (e.g. Zostavax® and Shingrix®), which may explain the increase in the IR for this condition following the first national COVID-19 lockdown. Furthermore, not having an unvaccinated control group limited the ability to exclude the effects of time-varying confounders. However, given the context, comparisons with time trends of a comparable unvaccinated control group were not possible. The effectiveness of COVID-19 vaccines can also differ in patients with immune-mediated conditions not investigated in this study and in those taking immunosuppressants.[49–52]

We could not distinguish between acute urticaria and CSU, because the diagnostic codes do not specify these variants. Clinically, this is a limitation because CSU is more burdensome than acute urticaria.[53] We suspect that most of the recorded urticaria diagnoses before the first national COVID-19 lockdown were acute variants due to their higher lifetime prevalence than the chronic variant.[54,55] The sudden decrease in the IR for urticaria could be attributed to patients managing urticaria with over-the-counter antihistamines during the national lockdown. Simultaneously, patients with CSU could have sought GP appointments following the lockdowns due to painful, prolonged symptoms that over-the-counter antihistamines could not resolve.[53] Hence, based on our data, we could not ascertain the proportion of patients with each urticaria variant. Unlike other population-based studies, we did not adjust for the SARS-CoV-2 infection in our analyses, which is known to be associated with HZ and BP.[56,57] Therefore, differentiating between virus-induced or vaccine-induced HZ and BP was not possible. However, the low autocorrelation in our models suggests that SARS-CoV-2 infections might not have had a large impact on the examined IRs at the whole population level.

While we did not detect a change in the BP IR following the COVID-19 vaccine programme, we found that the IRs for HZ and urticaria increased after the programme started vs. the

prevaccination period. However, these increases in IRs were modest, and, for many patients, the vaccination benefits will probably outweigh the potential risks. Further research should use individual patient-level studies, such as self-controlled case series, to determine whether the increases in the IRs for HZ and urticaria are driven by the COVID-19 vaccines.

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Conflicts of interest

During the course of this work, V.P. received salary funding via the University of Nottingham from the National Institute for Health and Care Research (NIHR) Senior Clinical Practitioner Research Award scheme. V.P. reports associations with King's College London and the University of Nottingham. M.J.R. is funded by an NIHR Research Professorship (NIHR303123). The other authors declare no conflicts of interest.

Data availability

Clinical Practice Research Datalink (CPRD) provided the data supporting this study's findings under a licence that does not permit sharing. The data are available by applying to CPRD directly via www.cprd.com.

Ethics statement

Data in the Clinical Practice Research Datalink are anonymized and provided to the researchers by the Medicines and Healthcare products Regulatory Authority after external peer review and approval by their Independent Scientific Advisory Committee.

Patient consent

Not applicable.

Supporting Information

Additional Supporting Information may be found in the online version of this article at the publisher's website.

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