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Rare adverse events after COVID-19 vaccination among Swedish older adults-evidence from a nationwide register-based study

Yiyi Xu [a,*], Fredrik Nyberg [a], Ulrika Marking [b,c], Magnus Gisslén [d,e], Jonas W. Wastesson [f,g], Kristina Johnell [f]

[a] School of Public Health and Community Medicine, Institute of Medicine, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden
[b] Department of Clinical Sciences, Karolinska Institutet Danderyd Hospital, Stockholm, Sweden
[c] Department of Public Health Analysis and Data Management, Public Health Agency of Sweden, Stockholm, Sweden
[d] Department of Infectious Diseases, Institute of Biomedicine, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden
[e] Department of Infectious Diseases, Sahlgrenska University Hospital, Region Västra Götaland, Gothenburg, Sweden
[f] Department of Medical Epidemiology and Biostatistics, Karolinska Institutet, Stockholm, Sweden
[g] Aging Research Center, Department of Neurobiology, Care Sciences and Society, Karolinska Institutet & Stockholm University, Stockholm, Sweden

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ABSTRACT

Introduction: COVID-19 vaccinations have saved millions of lives, particularly among older adults. Rare potential adverse events have been reported in case reports, but risks among older adults remain unclear. This study assessed risks of selected potential adverse events in this population.

Methods: We included more than 2 million Swedish adults ≥65y in a nationwide register-based cohort. Post-vaccination risks were assessed for herpes zoster (HZ), encephalitis, myelitis and encephalomyelitis, multiple sclerosis (MS), myasthenia gravis, cranial nerve palsy, sudden sensorineural hearing loss (SSNHL), postinfectious arthritis and polymyalgia rheumatica (PMR) in several risk windows (1–30, 31–60, and 61–180 days) after each vaccine dose. Hazard ratios (HRs) with 95% confidence intervals (95%CIs) compared with unvaccinated were estimated by Cox regression adjusted for potential confounders. Sensitivity analyses included adding primary health care (PHC) visits, and applying analysis-specific 5-year disease-free wash-out periods.

Results: No increased HRs were observed for most outcomes. SSNHL showed increased HRs within 180 days after each dose [1.60 (95%CI 1.15–2.24); 1.43 (1.03–1.99); 1.61 (1.05–2.46) for dose 1, 2 and 3], with similar estimates across all three risk windows. Increased HRs were also seen for PMR after dose 2 [1.14 (1.04–1.24)] and dose 3 [1.16 (1.03–1.30)], with higher HRs during later time windows. HZ showed increased HRs in the sensitivity analysis with PHC visits, [1.19 (1.07–1.31); 1.31 (1.19–1.43); 1.42 (1.26–1.60) for dose 1, 2 and 3]. MS showed reduced risk after dose 3 in the sensitivity analysis with longer wash-out (targeting incident MS), but not in the main analysis (potential relapses included).

Conclusions: COVID-19 vaccines are generally safe in older adults, with very low incidence of the potential rare adverse events assessed. Slightly increased relative risks for SSNHL, PMR and HZ were observed, but these findings do not alter the overall benefit–risk profile of COVID-19 vaccination in older adults.

1. Introduction

COVID-19 vaccines were developed at unprecedented speed and both clinical trials and observational studies have demonstrated that vaccination provides effective protection against severe COVID-19 [1,2], with older adults gaining the greatest benefit [3]. In the current COVID-19 endemicity, vaccination strategies in many countries focus almost exclusively on older adults, making safety evidence in this group especially important. The general safety of these vaccines was confirmed in randomized clinical trials (RCTs) [4] and have been further assessed in post-marketing surveillance. However, rare adverse events are difficult to assess in RCTs due to their low incidence rate and the limited follow-up time [5]. Moreover, RCTs often exclude important populations, such as older adults, young children, and pregnant women [6,7].

Post-marketing surveillance and case reports have documented rare

* Corresponding author at: BOX 453, School of Public Health and Community Medicine, University of Gothenburg, 40 530 Göteborg, Sweden.
E-mail address: yiyi.xu@amm.gu.se (Y. Xu).

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adverse events following COVID-19 vaccination. However, most of them are uncommon and not definitively linked causally to vaccination. A recent multinational cohort study including 99 million vaccinated individuals within the Global Vaccine Data Network reported potential safety signals for Guillain-Barré syndrome, cerebral venous sinus thrombosis and acute disseminated encephalomyelitis among 13 conditions studied [8]. Other neurological, autoimmune, and inflammatory conditions have been reported in temporal association with vaccination, including herpes zoster (HZ) [9], Polymyalgia rheumatica (PMR) [10,11], and sudden sensorineural hearing loss (SSNHL) [12]. These safety signals have primarily been studied in the general population across a wide age range. Although age-adjusted analyses are sometimes reported, the risks specifically among older adults remain unclear. Since the risk landscape is gradually shifting and vaccination efforts are largely concentrated to older adults, safety data in this population is highly relevant. To address this, we conducted a nationwide register-based cohort study including all Swedish older adults, assessing risks of selected rare adverse events after each COVID-19 vaccine dose. The study investigated HZ, cranial nerve palsy, PMR, encephalitis, multiple sclerosis (MS), myasthenia gravis, postinfectious arthritis and SSNHL, within predefined risk windows (1–30 days, 31–60 days and 61–180 days) after vaccination. For events with sufficient case numbers, we also explored risks by vaccine product, focusing on Comirnaty® (Pfizer), Spikevax® (Moderna) and Vaxzevira® (AZ), available in Sweden.

2. Materials and methods

2.1. Study design and data source

This is a Swedish nationwide register-based cohort study, conducted within the larger SCIFI-PEARL (Swedish COVID-19 Investigation for Future Insights – a Population Epidemiology Approach using Register Linkage) project. For the purposes of the current analyses, data from the following registers were used: COVID-19 infection was obtained from SmiNet, Sweden's national electronic surveillance system for notifiable communicable diseases [13]; vaccination data came from the National Vaccination Register; date and cause of death were obtained from the National Cause of Death Register (NCDR). In-patient and specialist outpatient healthcare data from 2015 onward, comprising a complete specialist care medical history for all individuals, were obtained from the National Patient Register (NPR).

For people living in Region Västra Götaland and Region Stockholm, the two largest regions in Sweden (40% of the population), additional healthcare data from 2015 onwards were obtained from the two regional databases covering all public and most private primary healthcare visits (VEGA and VAL). Sociodemographic data including education, family situation, income and occupational data from 2018 onward were obtained from the Statistics Sweden Longitudinal Integrated Database for Health Insurance and Labour Market Studies (LISA). Information on older adults living at special care facilities and/or receiving home care services was obtained from the National Social Service Register.

2.2. Study population, study period, exposure and risk windows

All individuals in the Swedish population with age $\geq$ 65 years at the study start (i.e., 27 December 2020), who also had lived in Sweden since 2015, were eligible for this study (to ensure a 6 year look back time for capturing disease history). The long look back period is important for older population as they generally have more chronic diseases. People with a studied rare event 6 months prior the study start (from 1 July 2019 to 26 December 2020) were excluded, and exclusion was based on each rare event separately for each specific analysis.

The complete study period was from 27 December 2020 (when first vaccination was available in Sweden) to 31 July 2024. Each individual was followed from study start to the earliest of: outcome date, next vaccination date, emigration, death, or study end. The exposure variables were each dose of any COVID-19 vaccine. With each vaccine dose, four mutually exclusive risk windows (1–30 days, 31–60 days, 61–180 days and $>$ 180 days) were defined to capture short-term and longer-term effects.

2.3. Outcomes

Outcomes were selected based on a combination of biological plausibility or mechanistic pathways potentially linking vaccination to adverse events (e.g., immune-mediated reactions), signals reported from pharmacovigilance systems and existing literature including clinical trials and prior observational studies [8–10]. All outcomes were defined using the Swedish clinical modification of the International Classification of Diseases, 10th revision (ICD-10-SE) (Table 1). Guillain-Barré syndrome, aseptic meningitis, and transverse myelitis were also initially considered, however, these conditions were excluded from analyses due to very few cases during the follow-up period (less than 100 cases during the whole study period).

Each outcome was defined as the first occurrence during the follow-up, identified by the recording of a primary or secondary diagnosis in the inpatient or outpatient specialist care data from the NPR, or as an underlying or contributing cause of death in the NCDR. In the sensitivity analyses including primary healthcare data for HZ, PMR and post-infectious arthritis (see details in Statistical analysis), additional recording of a primary or secondary diagnosis in the primary healthcare visits were also used for identifying first occurrence.

2.4. Covariates

Covariates selection was based on literature review including our previous studies in the same population [14], as well as studies on vaccine safety regarding other health outcomes [15,16]. The covariates included age, sex, country of birth, individual disposable income, education, marital status, cohabitant, long term care use, healthcare utilization before COVID-19, prior comorbidities before COVID-19, and COVID-19 infection. All covariates, except COVID-19 infection (time-varying), were defined as baseline covariates and were assessed on or before 1 January 2020. COVID-19 infection was time-varying and coded as "no" until the first positive SARS-CoV-2 PCR test was identified from SmiNet. The grouping and definition of categories are presented in the Supplemental Table S1.

Prior comorbidities before COVID-19 included clinical diagnosed cardiovascular diseases, respiratory diseases, diabetes, cancer, dementia, and mental disorders during 2015–2019, based on primary and secondary diagnoses from specialized outpatient visits and hospital admission data from the NPR. The prior comorbidities were defined using the ICD-10-SE, as listed in Supplemental Table S2.

Table 1
List of the International Classification of Diseases, 10th revision, Swedish version (ICD-10-SE) codes for the studied outcomes.

Disease	ICD-10-SE
Herpes zoster (HZ)	B02
Encephalitis, myelitis and encephalomyelitis	G04, G05
Multiple sclerosis and other demyelinating disorders (MS)	G35, G36, G37
Myasthenia gravis	G70.0
Cranial nerve palsy	H81.2, H49.2, J38.0, H49.1, G51.0, H46
Sudden sensorineural hearing loss (SSNHL)	H91.2
Postinfectious arthritis	M01.5 M01.8 M02 M03
Polymyalgia rheumatica (PMR)	M35.3

2.5. Statistical analysis

Cox proportional hazard models with time-varying exposure were used, applying calendar time as the underlying time scale. This approach accounts for temporal factors such as infection pressure and pandemic restrictions, since the risk sets were updated sequentially by calendar day. Each individual's follow-up time was divided according to vaccine status (unvaccinated, dose 1, dose 2, and dose 3) and further split into predefined risk windows within each dose. With this design, each individual contributed person-time as unvaccinated until their first vaccination. After each dose, individuals contributed person-time in each corresponding post-vaccination risk window (i.e., exposed risk-time).

The analyses were first performed for any vaccine product regardless of risk windows and estimated the overall hazard ratio (HR) for each outcome after each dose up to 180 days compared to unvaccinated person-time. We limited follow-up to 180 days after each dose as events occurring beyond six months after vaccination were considered unlikely to be vaccine related. Then, we estimated HRs for each risk window after each dose. Vaccine product-stratified analyses were performed for three vaccine products that were mainly used in Sweden: Comirnaty® (Pfizer), Spikevax® (Moderna) and Vaxzevira® (AZ), to estimate the overall HRs after each dose for the window up to 180 days (due to limited numbers).

Two additional sensitivity analyses were performed. First, for diagnoses commonly recorded in primary health care – HZ, postinfectious arthritis and PMR – we incorporated records from the regional databases (VEGA and VAL) in a subset of the study population with individuals living in the two regions (approximately 40% of the Swedish population). This approach improved the completeness and onset timing accuracy of cases identification (i.e., an initial primary health care visit followed by a specialist hospital visit) and reduced misclassification of cases that would otherwise be counted as non-cases if no specialist hospital visit was recorded in the NPR. Second, for diseases with a more chronic course – MS, myasthenia gravis, and PMR – we applied a longer, five-year diagnosis-free washout period to better capture true incident cases. Both sensitivity analyses used the same statistical approach as the main analysis.

HRs with 95% confidence intervals (CI) from the full models adjusted for all covariates mentioned are reported. HRs are not reported for time windows with less than five cases. All statistical analyses were performed using Stata, (version. 18.0; StataCorp LLC).

2.6. Ethical approval

This study obtained ethics approval from the Swedish Ethical Review Authority (2020–01800, 2020–05829, 2021–00267, 2021–00829, 2021–02106, 2021–04098, 2022–00500-02, 2022–01207-02, 2022–03323-02, 2023–00448-02, and 2023–00947-02). Consent to participate is not applicable because this study is register based.

3. Results

In total, more than 2 million older adults were included in this study (Table 2). The majority (94.8%) received at least one Covid vaccination dose by the end of follow-up on 31 July 2024. Older adults born in Sweden, with higher income, higher education, and were married or living with others were more likely to be vaccinated, whereas those receiving home care or residential care, or those with lower pre-pandemic healthcare utilization, were less likely to receive vaccination. Cardiovascular diseases were the most common health conditions, followed by respiratory diseases. Overall, health conditions were similar across vaccination groups. The number of eligible cases and incidence rate during the follow-up for each selected outcome are listed in Table 3. PMR showed highest incidence rate as 342.1 cases per 100,000 person-years, while encephalitis, myelitis and encephalomyelitis showed the lowest incidence rate (14.0 cases per 100,000 person-years).

Table 2
Baseline demographics and medical history in Swedish older adults (≥65 years) resident in Sweden on 27 Dec 2020, overall and by vaccine status at the end of follow-up.

	Vaccination status at the end of follow-up		Total
	Never vaccinated	At least one dose	
Counts	106,830 (5.2%)	1,966,260 (94.8%)	2,073,090 (100.0%)
Age			
65-74y	62,547 (58.5%)	1,119,530 (57.0%)	1,182,077 (57.0%)
75-84y	29,268 (27.4%)	639,489 (32.5%)	668,757 (32.3%)
85-94y	13,165 (12.3%)	193,182 (9.8%)	206,347 (10.0%)
≥ 95y	1850 (1.7%)	14,059 (0.7%)	15,909 (0.8%)
Sex			
Men	50,423 (47.2%)	914,742 (46.5%)	965,165 (46.6%)
Women	56,407 (52.8%)	1,051,518 (53.5%)	1,107,925 (53.4%)
Country of birth			
Sweden	71,423 (66.9%)	1,727,827 (87.9%)	1,799,250 (86.8%)
Nordic without Sweden	7627 (7.1%)	96,117 (4.9%)	103,744 (5.0%)
EU28 without Nordic	10,946 (10.2%)	55,842 (2.8%)	66,788 (3.2%)
Other countries	16,834 (15.8%)	86,474 (4.4%)	103,308 (5.0%)
Individual disposable income			
Low	71,805 (67.3%)	793,431 (40.4%)	865,236 (41.7%)
Median	24,161 (22.6%)	699,702 (35.6%)	723,863 (34.9%)
High	10,802 (10.1%)	473,115 (24.1%)	483,917 (23.3%)
Education			
Primary	37,508 (36.8%)	567,760 (29.1%)	605,268 (29.5%)
Upper secondary	42,211 (41.4%)	820,931 (42.1%)	863,142 (42.0%)
Tertiary	22,184 (21.8%)	562,668 (28.8%)	584,852 (28.5%)
Marital status			
Married and registered partner	35,758 (33.5%)	1,029,975 (52.4%)	1,065,733 (51.4%)
Not married or divorced or widow	71,072 (66.5%)	936,285 (47.6%)	1,007,357 (48.6%)
Cohabitant			
Living with others	55,149 (51.6%)	1,292,119 (65.7%)	1,347,268 (65.0%)
Living alone	51,123 (47.9%)	673,417 (34.2%)	724,540 (34.9%)
Unknown	558 (0.5%)	724 (0.0%)	1282 (0.1%)
Long term care use			
No use	88,735 (83.1%)	1,742,290 (88.6%)	1,831,025 (88.3%)
Receiving home care service	12,891 (12.1%)	151,928 (7.7%)	164,819 (8.0%)
Receiving residential care	5204 (4.9%)	72,042 (3.7%)	77,246 (3.7%)
Healthcare utilization before COVID-19			
No or limited	61,769 (57.8%)	969,564 (49.3%)	1,031,333 (49.7%)
Moderate utilization	31,816 (29.8%)	790,048 (40.2%)	821,864 (39.6%)
Extensive utilization	13,245 (12.4%)	206,648 (10.5%)	219,893 (10.6%)
Respiratory diseases			
No	87,509 (81.9%)	1,657,192 (84.3%)	1,744,701 (84.2%)
Yes	19,321 (18.1%)	309,068 (15.7%)	328,389 (15.8%)
Cardiovascular diseases			

(continued on next page)

Table 2 (*continued*)

	Vaccination status at the end of follow-up		Total
	Never vaccinated	At least one dose	
	64,415	1,127,935	1,192,350
No	(60.3%)	(57.4%)	(57.5%)
	42,415	838,325	880,740
Yes	(39.7%)	(42.6%)	(42.5%)
Dementia			
	103,580	1,917,257	2,020,837
No	(97.0%)	(97.5%)	(97.5%)
Yes	3250 (3.0%)	49,003 (2.5%)	52,253 (2.5%)
Diabetes			
	94,655	1,758,288	1,852,943
No	(88.6%)	(89.4%)	(89.4%)
	12,175	207,972	220,147
Yes	(11.4%)	(10.6%)	(10.6%)
Mental disorders			
	102,026	1,908,283	2,010,309
No	(95.5%)	(97.1%)	(97.0%)
Yes	4804 (4.5%)	57,977 (2.9%)	62,781 (3.0%)
Cancer			
	91,742	1,630,676	1,722,418
No	(85.9%)	(82.9%)	(83.1%)
	15,088	335,584	350,672
Yes	(14.1%)	(17.1%)	(16.9%)

Among all eight outcomes investigated (Fig. 1), most showed no clear or moderate associations with vaccination in the main analysis. Moderate increased risks of SSNHL were observed after each dose, with HR 1.60 (95%CI 1.15–2.24) for dose 1; 1.43 (1.03–1.99) for dose 2; and 1.61 (1.05–2.46) for dose 3. Within each dose, all three risk windows showed similar risk estimates. Additionally, increased risks were observed for PMR after dose 2 and dose 3, with a pattern of slightly higher risks the later risk windows. For instance, the HRs increased from 1.13 (1.02–1.25) during 0–30 days to 1.26 (1.14–1.38) during 61–180 days after dose 2. For encephalitis, myelitis and encephalomyelitis, there seemed to be a reduced risk after dose 3, however the 95%CIs were very wide due to limited number of cases. For the remaining outcomes, no clear associations between vaccination and risks of the diseases were observed.

In the sensitivity analysis including primary healthcare visits for HZ, postinfectious arthritis and PMR, incidence rates increased dramatically, especially for HZ that showed incidence rate as 903.8 cases per 100,000 person-year compared to 140.4 in the main analysis only including specialist hospital visits (Table 3). The evidence of increased risks of PMR after vaccination became stronger (Fig. 2). HZ also showed increased risks after all three doses and there was a trend of higher risks in the later risk windows, which was not seen in the main analysis. For postinfectious arthritis, as in the main analysis, no clear pattern of increased risks was observed (Fig. 2).

When restricting analyses to individuals without a prior diagnosis of the outcome in the preceding five years (Fig. 3), patterns were similar to the main analysis. PMR, continued to show modest associations, although the incident case numbers were markedly lower. Myasthenia gravis again showed no association with vaccination. For MS, however, the estimates were different from the main analysis, showing an indication of decreased risks after vaccination. However, the estimates were very imprecise due to limited number of cases.

Due to limited number of cases, the vaccine product stratified analysis had more limited power and was only performed to obtain overall HRs after each dose up to 180 days (Table 4). For SSNHL, significantly higher risks were observed for mRNA vaccines, especially after dose 3. The two mRNA vaccines also seemed to be associated with increased risks for PMR after dose 2 and dose 3, as well as for MS after dose 2. For other events, no statistically significant associations were observed. Fig. 4 summarized all results from all analyses.

4. Discussion

In this nationwide register-based study of more than two million older adults, the population group that is now the primary target of COVID-19 vaccination programs, we investigate safety signals associated to vaccination. We confirm the vaccines to be safe and with a maintained risk-benefit profile but found moderate and partly inconsistent signals (Fig. 4). For most of the conditions (encephalitis, myelitis and encephalomyelitis, myasthenia gravis, cranial nerve palsy and postinfectious arthritis), our study did not find any supportive evidence for increased risk. For PMR, HZ and SSNHL, modestly increased risks were suggested after COVID-19 vaccination. Weak evidence was also noted for postinfectious arthritis. For MS, results differed depending on the analytical approach, underlining the uncertainty in interpreting findings for chronic relapsing conditions. Overall, the results support the continued use of COVID-19 vaccines in older adults, while highlighting the importance of ongoing surveillance for rare adverse events.

For most of the investigated outcomes, no associations were observed between COVID-19 vaccination and risk of disease, providing overall reassurance regarding vaccine safety in older adults. For PMR, a moderate positive association was observed after vaccination across all analyses, with slightly higher estimates in later risk widows. PMR is a common inflammatory rheumatic diseases in older adults, and infections or vaccinations may act as immune triggers [17,18]. Previous studies have described PMR after influenza and RSV vaccines [17] [19]. Pharmacovigilance analyses during the COVID-19 pandemic, also suggested elevated reporting odds, though generally lower than for influenza vaccines [11]. A recent population-based study found a small but

Table 3
Number of eligible cases and incidence rate (per 100,000 person-years) of each selected rare events after vaccination included in the main analysis and the two sensitivity analyses, respectively.

Rare events	Main analysis [a]		Sensitivity analysis 1 [b]		Sensitivity analysis 2 [c]	
	Cases	Incidence rate	Cases	Incidence rate	Cases	Incidence rate
Herpes zoster (HZ)	3857	140.4	8732	903.8	n.a.	
Encephalitis, myelitis and encephalomyelitis	384	14.0	n.a.		n.a.	
Multiple sclerosis and other demyelinating disorders (MS)	1991	72.5	n.a.		210	7.7
Myasthenia gravis	628	22.8	n.a.		215	7.8
Cranial nerve palsy	5676	206.8	n.a.		n.a.	
Sudden sensorineural hearing loss (SSNHL)	923	33.6	n.a.		n.a.	
Postinfectious arthritis	640	23.3	567	58.3	n.a.	
Polymyalgia rheumatica (PMR)	9369	342.1	6911	721.6	5562	204.7

a. Main analysis included all older adults (≥65 years) resident in Sweden on 27 Dec 2020 and followed until 31 July 2024.
b. Sensitivity analysis 1 incorporated records from the regional databases (VEGA and VAL) with primary health care data. This analysis only included Swedish older adults (≥65 years) resident in Region Stockholm and Region Västra Götaland (about 40% of all Swedish population).
c. Sensitivity analysis 2 applied longer, 5-year diagnosis-free washout period. This analysis included all Swedish older adults (≥65 years).
n.a.: Not applicable. No sensitivity analysis was performed for these rare events.

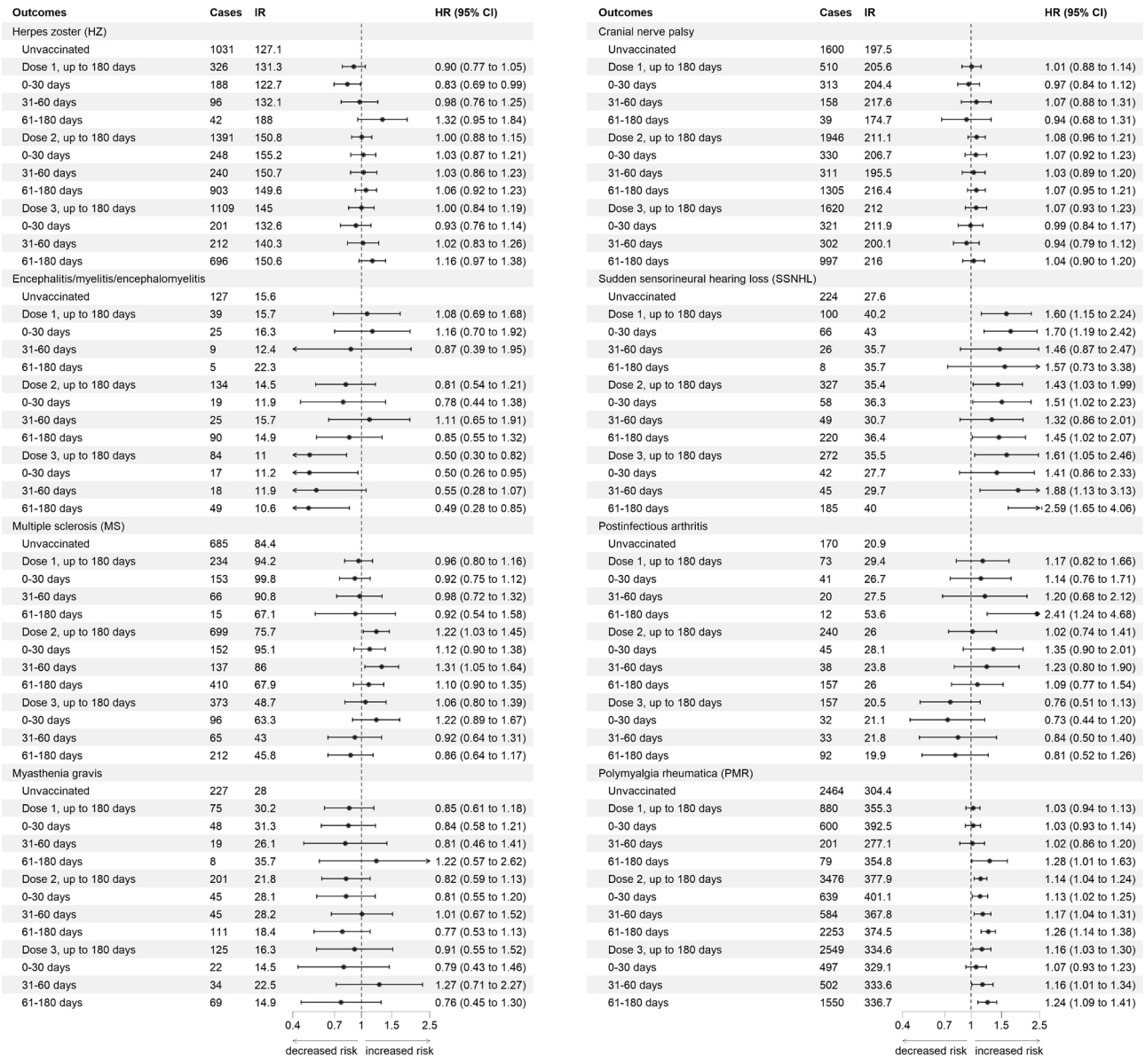

Fig. 1. Hazard ratios (dots) and 95% confidence intervals (lines) for overall risks up to 180 days after each dose, and for each risk window for the investigated rare events. All events used composite endpoints, including specialist outpatient visits, hospital admissions, and deaths. HR and 95% CI were obtained from a fully adjusted model. HR and 95%CI for cases ≤5 were omitted. *IR: incidence rate, per 100,000 person-years; HR: hazard ratio; CI: confidence interval.*

measurable increase in incident PMR after BNT162b2 vaccine (HR 2.1), although the risk remained low in absolute terms [20]. Our findings are broadly consistent with this literature, but the associations were modest (HRs around 1.5) and absolute risks remain low.

An increased risk was observed for HZ shortly after each dose of COVID-19 vaccination only in the sensitivity analysis that also included outcomes in primary care. As HZ is typically diagnosed in primary care these findings are likely more accurate than those based only on specialist care records. Naturally, the number of HZ cases was larger in the sensitivity analysis than in the main analysis even though the total population denominator was larger in the main analysis. Existing evidence remains mixed: while case reports and small series have described temporal clusters of HZ shortly after COVID-19 vaccination [21,22], large scale register-based studies have found either no association or small relative increases corresponding to very low absolute risk [23–25]. A recent Dutch study based on general practice data from more than 2 million vaccinated individuals reported a small increased risk of HZ in general and specifically after the third dose with mRNA vaccines [25]. Our results are consistent with this pattern, providing weak evidence of a possible association and should be interpreted with caution.

Sporadic case reports and pharmacovigilance analyses have suggested a possible signal for SSNHL after COVID-19 vaccination. [26,27]. Larger register-based and cohort studies, however, have found no or only small associations, with pooled analyses concluding that there is no strong evidence overall [12,28]. In our study we observed elevated risks across all three doses, but case numbers were small and estimates imprecise, similar to the previous studies. Given the rarity of SSNHL and the clear protective effects of vaccination against severe COVID-19, any potential impact is limited and should not influence current recommendations.

Our study yielded inconsistent findings for MS. In the main analysis with 6-month diagnosis-free washout period, an increased risk of MS was noted after dose 2. However, in the sensitivity analysis with 5-year wash-out period, a decreased risk was observed. The inconsistency complicates interpretation and may reflect the relapsing nature of MS. A shorter wash-out might be more likely to capture MS relapse, while a

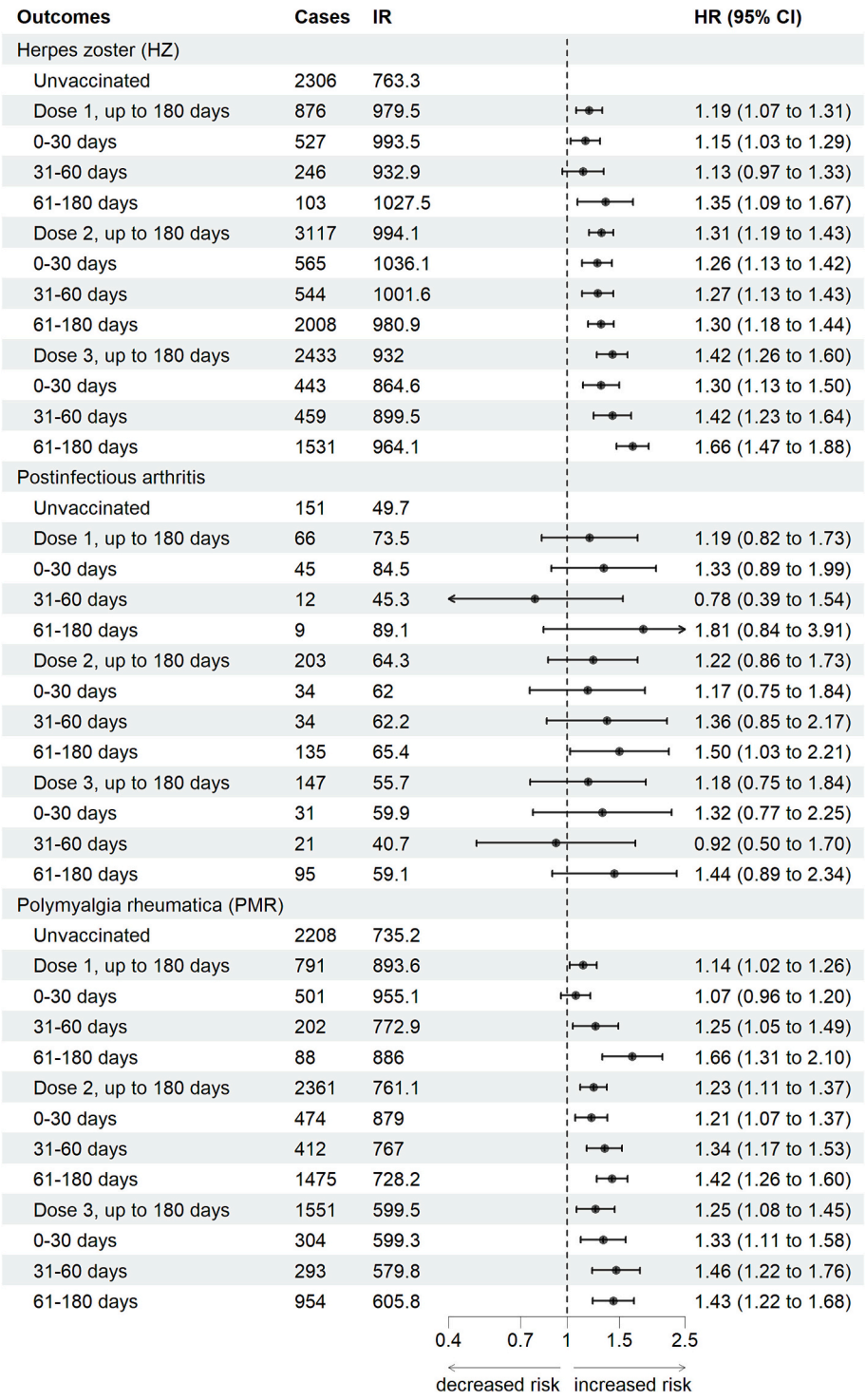

Fig. 2. Hazard ratios (dots) and 95% confidence intervals (lines) for overall risks up to 180 days after each dose, and for each risk window for herpes zoster, postinfectious arthritis, and polymyalgia rheumatica. All events used composite endpoints, including **primary healthcare visits**, specialist outpatient visits, hospital admissions, and deaths. HR and 95% CI were obtained from a fully adjusted model in a restricted study population with people lived in Region Västra Götaland and Region Stockholm (covering about 40% of the Swedish population). *IR: incidence rate, per 100,000 person-years; HR: hazard ratio; CI: confidence interval.*

longer wash-out might better approximates new incident MS or at least very inactive longstanding MS. Previous studies of COVID-19 vaccination and MS mainly focused on relapse and found no association [29–31]. Given that COVID-19 infection itself can trigger MS exacerbations [32], the potential protective effects against MS may be an indirect protective effect that through the protective effects against COVID-19 infection, rather than a direct vaccine effect of reducing MS disease activity.

It should be noted that even though we found modest increased risks of PMR, HZ and SSNHL following COVID-19 vaccination, the absolute risks were very low. These findings do not appreciably change the overall benefit–risk profile of COVID-19 vaccines, especially in older adults at high risk from COVID-19 infection and hospitalization. However, the recurring HZ signal across observational studies suggests that continued pharmacovigilance and regulatory review of the accumulating evidence may be warranted.

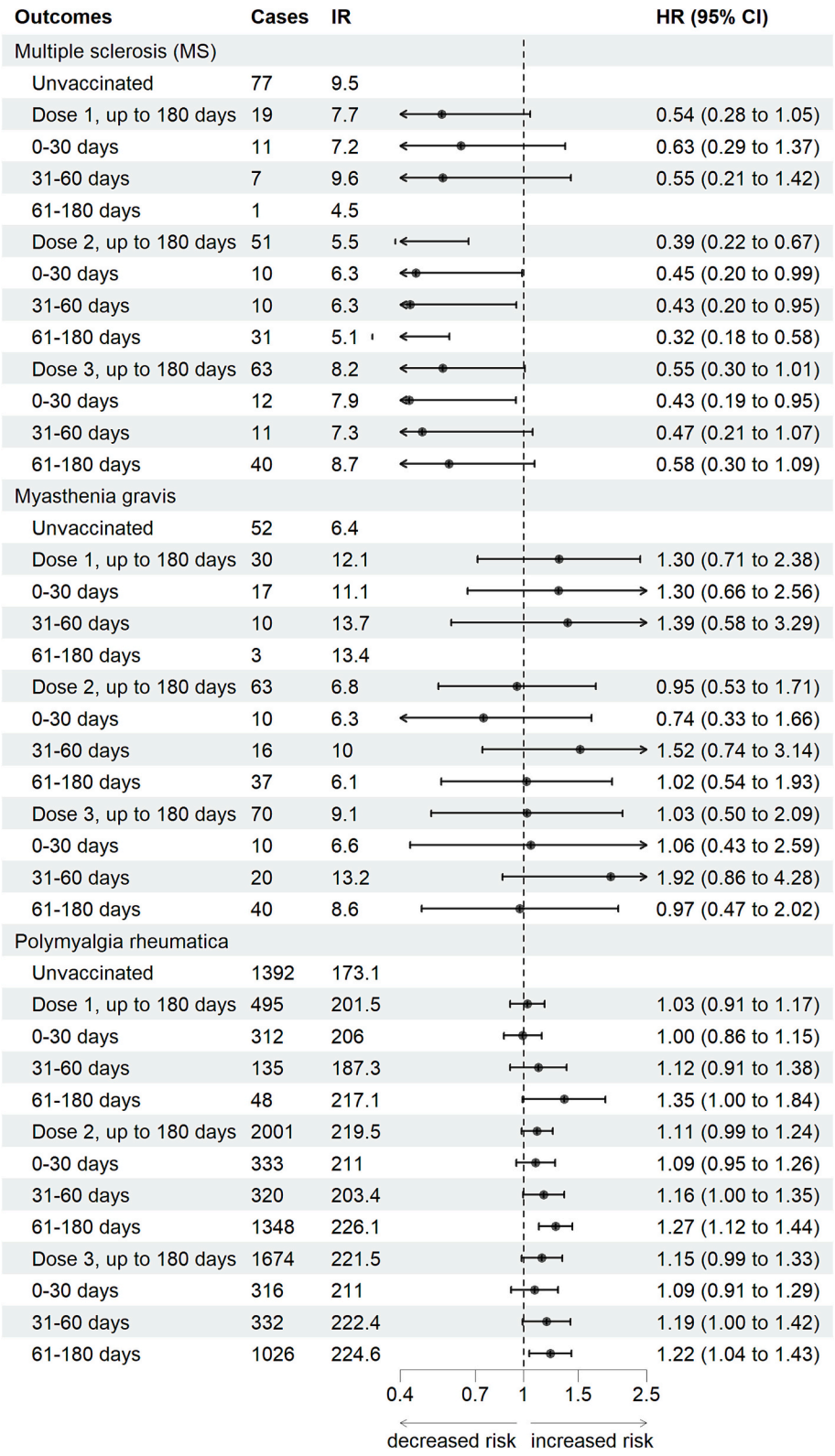

Fig. 3. Hazard ratios (dots) and 95% confidence intervals (lines) for overall risks up to 180 days after each dose, and for each risk window for multiple sclerosis, myasthenia gravis and polymyalgia rheumatica. All events used composite endpoints, including specialist outpatient visits, hospital admissions, and deaths. HR and 95% CI were obtained from a fully adjusted model in the study population who had **no registered diagnosis of the certain event in the 5 years prior the study start.** HR and 95%CI for cases ≤5 were omitted. *IR: incidence rate, per 100,000 person-years; HR: hazard ratio; CI: confidence interval.*

Table 4
Hazard ratios (HR) with 95% confidence interval (CI) for selected rare events after vaccination among Swedish older adults (≥65 years) resident in Sweden on 27 Dec 2020 and followed until 31 July 2024, by dose and specific vaccine products, within a 180-day risk window after each vaccination.

Risk window	Person-years	Cases	Incidence rate	Full model [a]
			(Per 100,000 person-years)	HR (95%CI)
Herpes zoster (HZ)				
Unvaccinated	811,013	1031	127	Ref
Dose 1, up to 180 days				
BNT162b2	134,964	174	129	0.84 (0.69, 1.02)
mRNA-1273	971,483	29	3	0.96 (0.65, 1.4)
AZD1222	94,923	123	130	0.96 (0.75, 1.23)
Dose 2, up to 180 days				
BNT162b2	622,395	988	159	1.07 (0.92, 1.25)
mRNA-1273	81,002	988	1220	1.15 (0.93, 1.43)
AZD1222	219,236	255	116	1.01 (0.83, 1.23)
Dose 3, up to 180 days				
BNT162b2	605,483	873	144	0.98 (0.79, 1.21)
mRNA-1273	159,339	236	148	1.04 (0.82, 1.32)
AZD1222	52	0		
Encephalitis, myelitis and encephalomyelitis				
Unvaccinated	812,007	127	16	Ref
Dose 1, up to 180 days				
BNT162b2	135,109	23	17	1.07 (0.62, 1.82)
mRNA-1273	972,688	2	0	0.66 (0.16, 2.76)
AZD1222	95,008	14	15	1.01 (0.49, 2.1)
Dose 2, up to 180 days				
BNT162b2	623,296	94	15	0.89 (0.56, 1.39)
mRNA-1273	81,137	94	116	0.82 (0.4, 1.69)
AZD1222	219,492	28	13	0.71 (0.4, 1.28)
Dose 3, up to 180 days				
BNT162b2	606,722	66	11	0.47 (0.26, 0.85)
mRNA-1273	159,671	18	11	0.5 (0.25, 1.02)
AZD1222	53	0		
Multiple sclerosis and other demyelinating disorders (MS)				
Unvaccinated	811,188	685	84	Ref
Dose 1, up to 180 days				
BNT162b2	134,958	124	92	0.93 (0.73, 1.18)
mRNA-1273	971,672	13	1	0.84 (0.48, 1.48)
AZD1222	94,910	97	102	1.12 (0.84, 1.51)
Dose 2, up to 180 days				
BNT162b2	622,456	516	83	1.34 (1.1, 1.63)
mRNA-1273	81,039	516	637	1.48 (1.09, 2)
AZD1222	219,234	119	54	1.09 (0.83, 1.43)
Dose 3, up to 180 days				
BNT162b2	605,746	305	50	0.83 (0.59, 1.16)
mRNA-1273	159,444	68	43	0.72 (0.48, 1.06)
AZD1222	53	0		
Myasthenia gravis				
Unvaccinated	811,829	227	28	
Dose 1, up to 180 days				Ref
BNT162b2	135,067	48	36	1.05 (0.71, 1.56)
mRNA-1273	972,451	3	0	0.47 (0.15, 1.5)
AZD1222	94,986	24	25	0.83 (0.48, 1.44)
Dose 2, up to 180 days				
BNT162b2	623,061	137	22	0.8 (0.55, 1.16)
mRNA-1273	81,102	137	169	1.17 (0.71, 1.95)
AZD1222	219,428	37	17	0.93 (0.56, 1.52)
Dose 3, up to 180 days				
BNT162b2	606,491	102	17	0.97 (0.5, 1.87)
mRNA-1273	159,600	23	14	0.79 (0.37, 1.68)
AZD1222	53	0		
Cranial nerve palsy				
Unvaccinated	810,282	1600	197	Ref
Dose 1, up to 180 days				
BNT162b2	134,847	291	216	1.11 (0.95, 1.31)
mRNA-1273	970,599	30	3	0.79 (0.55, 1.15)
AZD1222	94,836	189	199	1.12 (0.91, 1.38)
Dose 2, up to 180 days				
BNT162b2	621,846	1339	215	1.04 (0.92, 1.19)
mRNA-1273	80,937	1339	1654	1.07 (0.89, 1.29)

(*continued on next page*)

Table 4 (*continued*)

Risk window	Person-years	Cases	Incidence rate (Per 100,000 person-years)	Full model [a] HR (95%CI)
AZD1222	218,989	417	190	0.95 (0.81, 1.12)
Dose 3, up to 180 days				
BNT162b2	604,735	1272	210	1.05 (0.88, 1.25)
mRNA-1273	159,138	348	219	1.09 (0.89, 1.32)
AZD1222	53	0		
Sudden sensorineural hearing loss (SSNHL)				
Unvaccinated	811,868	224	28	Ref
Dose 1, up to 180 days				
BNT162b2	135,089	49	36	1.32 (0.88, 2)
mRNA-1273	972,523	12	1	2.25 (1.2, 4.24)
AZD1222	94,979	39	41	1.36 (0.84, 2.21)
Dose 2, up to 180 days				
BNT162b2	623,137	207	33	1.34 (0.91, 1.99)
mRNA-1273	81,113	207	255	0.97 (0.55, 1.72)
AZD1222	219,397	99	45	1.55 (1, 2.41)
Dose 3, up to 180 days				
BNT162b2	606,469	215	35	2.33 (1.25, 4.35)
mRNA-1273	159,592	57	36	2.33 (1.2, 4.53)
AZD1222	53	0		
Postinfectious arthritis				
Unvaccinated	811,901	170	21	Ref
Dose 1, up to 180 days				
BNT162b2	135,099	36	27	1.06 (0.68, 1.65)
mRNA-1273	972,558	3	0	0.66 (0.21, 2.13)
AZD1222	94,995	34	36	1.57 (0.93, 2.67)
Dose 2, up to 180 days				
BNT162b2	623,213	157	25	1.04 (0.72, 1.51)
mRNA-1273	81,125	157	194	1.24 (0.74, 2.09)
AZD1222	219,447	58	26	1.13 (0.72, 1.77)
Dose 3, up to 180 days				
BNT162b2	606,581	130	21	0.99 (0.59, 1.68)
mRNA-1273	159,641	27	17	0.79 (0.43, 1.47)
AZD1222	53	0		
Polymyalgia rheumatica (PMR)				
Unvaccinated	809,561	2464	304	Ref
Dose 1, up to 180 days				
BNT162b2	134,574	547	406	0.96 (0.86, 1.07)
mRNA-1273	969,566	83	9	1.01 (0.8, 1.27)
AZD1222	94,747	250	264	0.96 (0.82, 1.14)
Dose 2, up to 180 days				
BNT162b2	620,161	2610	421	1.1 (1, 1.21)
mRNA-1273	80,714	2610	3234	1.15 (1, 1.32)
AZD1222	218,772	500	229	0.97 (0.85, 1.11)
Dose 3, up to 180 days				
BNT162b2	602,989	2043	339	1.14 (0.97, 1.34)
mRNA-1273	158,700	506	319	1.13 (0.94, 1.35)
AZD1222	53	0		

a. Full model included age, sex, country of birth, individual disposable income, education, marital status, cohabitant, long term care use, healthcare utilization before COVID-19, prior comorbidities before COVID-19, and COVID-19 infection as adjustments.
HR: hazard ratio; CI: confidence interval.

The strengths of this study include its nationwide cohort design with over two million older adults, complete follow-up through linked registers, and the ability to assess rare outcomes within defined risk windows. Access to both specialist and primary care data improved case capture, particularly for conditions typically diagnosed in primary care.

Limitations common to register-based studies should be acknowledged. Lifestyle factors such as smoking, physical activity, or attitudes toward vaccination were not available and are potential confounders. We did adjust for sociodemographic variables from multiple linked registers with full national coverage, but residual confounding cannot be excluded. Outcome misclassification and the possibility of chance findings due to multiple testing also remain. Taken together, these strengths and limitations provide confidence in the overall results, while highlighting the need for cautious interpretation of modest associations.

5. Conclusion

In this complete nationwide cohort study, we confirm COVID-19 vaccines to be overall safe in older adults but report modest association for PMR and weaker evidence for HZ and SSNHL after vaccination. However, these outcomes were all rare in this elderly population. Given the substantial protection against severe COVID-19 provided by vaccination, the overall benefit-risk profile remains clearly favorable in older adults. These findings support ongoing vaccination targeting older adults with continued pharmacovigilance and regulatory review.

CRediT authorship contribution statement

Yiyi Xu: Writing – review & editing, Writing – original draft, Visualization, Methodology, Formal analysis, Data curation,

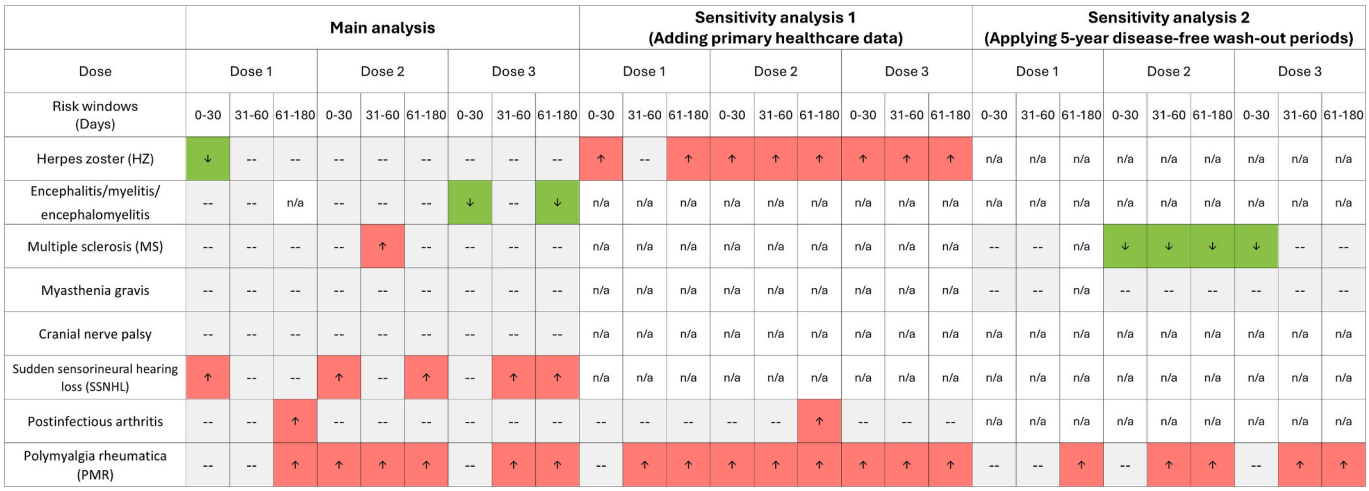

Fig. 4. Overview of the results from the main analysis and the two sensitivity analyses. Upward arrow in red cells indicates an increased risk. Downward arrow in yellow cells indicates a decreased risk. Double hyphen in grey cells indicates no significant association. n/a in white cells indicates not reported due to number of cases ≤5. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

Conceptualization. **Fredrik Nyberg:** Writing – review & editing, Methodology, Investigation, Funding acquisition, Data curation, Conceptualization. **Ulrika Marking:** Writing – review & editing, Validation, Investigation. **Magnus Gisslén:** Writing – review & editing, Validation, Investigation, Funding acquisition. **Jonas W. Wastesson:** Writing – review & editing, Validation, Methodology, Investigation, Funding acquisition, Conceptualization. **Kristina Johnell:** Writing – review & editing, Validation, Investigation, Funding acquisition, Conceptualization.

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Declaration of competing interest

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.vaccine.2026.128724.

Data availability

This study used pseudonymized individual-level data from Swedish healthcare registers that are not publicly available according to The Public Access to Information and Secrecy Act in Sweden. The data can be obtained from the respective Swedish data holders on the basis of ethics approval for the research in question, subject to relevant legislation, processes and data protection. Analysis coding can be available by request to the corresponding author.

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