Safety of COVID-19 Vaccines Among People with Prior History of SARS-CoV-2 Infection: Results from the Covid-Vaccine-Monitor Cohort Event Monitoring

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CONFLICT OF INTEREST STATEMENT

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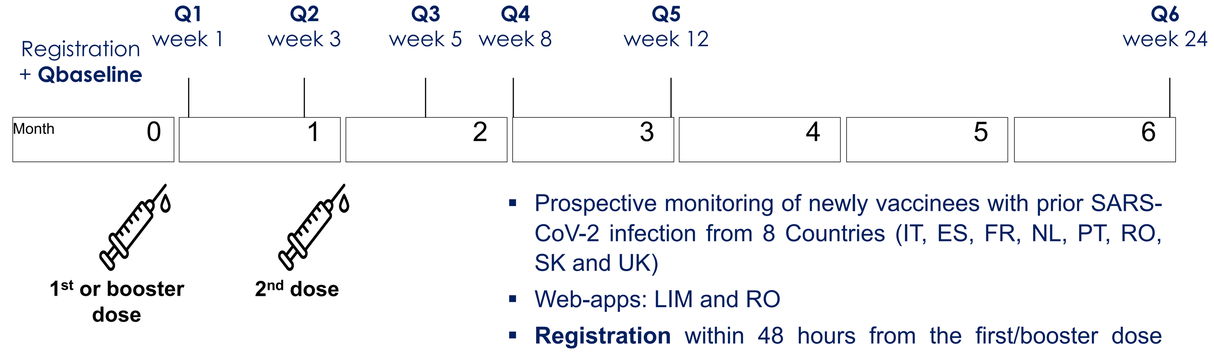
BACKGROUND

Real-world evidence on safety of COVID-19 vaccines in special cohorts is needed to integrate evidence from pivotal RCT.

OBJECTIVES

To investigate the frequency of local/systemic solicited and serious ADRs following the first, second and booster doses in people with prior SARS-CoV-2 infection vs. no prior SARS-CoV-2 infection, from February 2021 to December 2022.

METHODS



- Prospective monitoring of newly vaccinees with prior SARS-CoV-2 infection from 8 Countries (IT, ES, FR, NL, PT, RO, SK and UK)
- Web-apps: LIM and RO
- **Registration** within 48 hours from the first/booster dose administration

RESULTS

Table 1. Local and systemic solicited ADRs reported following the first, second and booster dose of COVID-19 vaccines.

	AstraZeneca			BioNTech/ Pfizer			Janssen	Moderna			All vaccines		
	1st dose	2nd dose	booster	1st dose	2nd dose	booster	1st dose	1st dose	2nd dose	booster	1st dose	2nd dose	booster
N. of participants	963 (100)	372 (100)	3 (100)	907 (100)	367 (100)	477 (100)	272 (100)	440 (100)	168 (100)	345 (100)	2594 (100)	910 (100)	827 (100)
At least one ADR	763 (79.2)	183 (49.2)	2 (66.7)	437 (48.2)	200 (54.5)	289 (60.6)	246 (90.4)	266 (60.5)	138 (82.1)	247 (71.6)	1719 (66.3)	522 (57.4)	540 (65.3)
Local solicited ADR (MedDRA PT), n (%)													
Injection site erythema	96 (10.0)	13 (3.5)	-	25 (2.8)	11 (3.0)	26 (5.5)	18 (6.6)	41 (9.3)	22 (13.1)	44 (5.3)	180 (6.9)	46 (5.1)	44 (5.3)
Injection site inflammation	218 (22.6)	33 (8.9)	-	82 (9.0)	22 (6.0)	69 (14.5)	55 (20.2)	80 (18.2)	43 (25.6)	124 (15)	437 (16.8)	98 (10.8)	124 (15)
Injection site pain	453 (47.0)	99 (26.6)	-	263 (29.0)	96 (26.0)	187 (39.2)	121 (44.5)	165 (37.5)	76 (45.2)	345 (41.7)	1006 (38.8)	272 (29.9)	345 (41.7)
Injection site swelling	184 (19.1)	23 (6.2)	-	62 (6.8)	21 (5.7)	53 (11.1)	48 (17.6)	78 (17.7)	33 (19.6)	111 (13.4)	373 (14.4)	77 (8.5)	111 (13.4)
Injection site warmth	141 (14.6)	20 (5.4)	-	55 (6.1)	16 (4.3)	40 (8.4)	25 (9.2)	53 (12)	27 (16.1)	68 (8.2)	275 (10.6)	63 (6.9)	68 (8.2)
Systemic solicited ADR (MedDRA PT), n (%)													
Arthralgia	260 (27.0)	20 (5.4)	-	61 (6.7)	33 (8.9)	69 (14.5)	72 (26.5)	61 (13.9)	35 (20.8)	120 (14.5)	456 (17.6)	88 (9.7)	107 (12.9)
Chills	496 (51.5)	33 (8.9)	1 (33.3)	112 (12.3)	53 (14.4)	103 (21.6)	116 (42.6)	104 (23.6)	58 (34.5)	199 (24.1)	830 (32.0)	144 (15.8)	148 (17.9)
Fatigue	498 (51.7)	78 (21.0)	1 (33.3)	211 (23.3)	91 (24.7)	175 (36.7)	165 (60.7)	159 (36.1)	81 (48.2)	320 (38.7)	1036 (39.9)	250 (27.5)	278 (33.6)
Headache	536 (55.7)	80 (21.5)	-	184 (20.3)	79 (21.4)	108 (22.6)	166 (61)	128 (29.1)	63 (37.5)	231 (27.9)	1019 (39.3)	222 (24.4)	229 (27.7)
Malaise	535 (55.6)	63 (16.9)	1 (33.3)	165 (18.2)	103 (27.9)	115 (24.1)	154 (56.6)	158 (35.9)	91 (54.2)	220 (26.6)	1014 (39.1)	257 (28.2)	200 (24.2)
Myalgia	485 (50.4)	59 (15.9)	2 (66.7)	219 (24.1)	72 (19.5)	122 (25.6)	153 (56.3)	160 (36.4)	73 (43.5)	226 (27.3)	1020 (39.3)	205 (22.5)	211 (25.5)
Nausea	232 (24.1)	21 (5.6)	-	66 (7.3)	32 (8.7)	44 (9.2)	63 (23.2)	70 (15.9)	39 (23.2)	85 (10.3)	434 (16.7)	92 (10.1)	56 (6.8)
Pyrexia	12 (1.2)	-	1 (33.3)	-	1 (0.3)	55 (11.5)	2 (0.7)	1 (0.2)	-	117 (14.1)	685 (26.4)	123 (13.5)	98 (11.9)
Hyperpyrexia	404 (42)	22 (5.9)	-	73 (8)	45 (12.2)	1 (0.2)	109 (40.1)	97 (22)	56 (33.3)	1 (0.1)	15 (0.6)	1 (0.1)	-

Serious ADRs occurred in **0.2% and 0.1%** of vaccinees following doses 1 and 2, respectively, and **0.1%** following the booster dose.
As for the general population ($N_{dose\ 1}$= 30,175; $N_{dose\ 2}$= 20,560), 67.7% and 49.1% reported ≥1 ADR following doses 1 and 2, respectively. The most commonly reported local/systemic ADRs following doses 1 and 2, across all vaccine brands, were injection site pain (36.2% vs. 21.9%), fatigue (35.7% vs. 23.2%), headache (33.1% vs. 17.9%), myalgia (32.9% vs. 18.5%) and malaise (30.9% vs. 19.0%). Serious ADRs were reported following doses 1 and 2, respectively, in 0.2% and 0.1% of vaccinees.

CONCLUSIONS

Overall, descriptive analysis showed a high frequency of local/systemic ADRs after dose 1 of any vaccine in subjects with previous COVID-19, with lower rates after dose 2. However, higher rates of local/systemic ADRs were observed after booster as compared to dose 2 of any vaccine. Findings from this study suggested that people with prior SARS-CoV-2 infection have a higher reactogenicity as compared to people with no prior SARS-CoV-2 infection, in line with the previous literature.