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Research Article

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Safety Profile of Covid-19 Vaccines: Retrospective Analysis of Short, Medium, and Long-Term Side Effects: The Military Hospital Experience

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Abstract

The retrospective study conducted at the Military Polyclinic of Rome "Celio" confirms the high safety profile of COVID-19 vaccines administered between 2020 and 2023. Among 41,276 doses, 41 adverse reactions (0.1%) were recorded, aligning closely with the national rate reported by AIFA (0.097%). Most reactions (92.7%) were non-severe; severe events (7.3%) were rare and occurred mainly in individuals aged 30–49. Adverse reactions primarily affected the musculoskeletal (29.2%) and immune systems (26.8%), with a greater incidence in female subjects (66%). The majority occurred after the first dose, consistent with national trends. Vaccine distribution showed minor local deviations from national averages, notably a slightly higher use of Moderna and lower of Pfizer. Ongoing pharmacovigilance by AIFA and EMA continues to ensure safety, with no evidence to date of medium- or long-term risks. Current data supports the effectiveness and safety of vaccination in preventing severe disease, hospitalization, and death, especially in vulnerable populations. The benefits of COVID-19 vaccination clearly outweigh its risks.

Keywords: COVID-19 Vaccines, Adverse Reactions, Pharmacovigilance, Safety Profile, Retrospective Analysis, Pfizer.

Introduction

Vaccinations are among the most effective strategies to reduce infectious disease incidence and prevent millions of deaths. Advances in science and technology have shifted the medical focus from treatment to prevention, enabling the management and control of global epidemics and pandemics, including smallpox and influenza. The COVID-19 pandemic posed an unprecedented global challenge, requiring rapid interventions. Vaccination emerged as a key tool to reduce transmission, severity, hospitalizations, and deaths, aiding the return to normalcy [1-5].

Purpose of the Study

This study aimed to analyze adverse reactions reported in Italy between 2020 and 2023 following the administration of authorized COVID-19 vaccines. Variables examined included sex, age, vaccine type, and dose number. Results were compared with national (AIFA) and European (EMA) pharmacovigilance data to identify possible correlations and assess consistency with broader trends [6].

Materials and Methods

A retrospective observational study was conducted on data collected from January 1, 2021, to December 31, 2023, at the Rome Military Hospital.

The study presented in this paper was approved by the Direction of the Military Polyclinic of Rome "Celio" and the Italian Army Health Command. The study was a retrospective analysis of data

related to COVID-19 vaccine administrations considering the time period between 2020 and 2023, in which the doses administered were distributed among five different types of vaccines: Pfizer (PF); AstraZeneca (AZ); Moderna (MO); Johnson&Johnson (JJ); Novavax (NVX) [7, 8].

The data presented here come from the National Pharmacovigilance Network (RNF), the Italian system dedicated to reporting and monitoring adverse reactions to drugs and vaccines, considering:

- Total number of doses administered for each vaccine
- Reports of adverse reactions, classified by severity and type
- Demographic distribution of vaccinated subjects (sex, age groups)
- Type of vaccine (PF; AZ; MO; JJ; NVX)
- Number of doses administered for primary cycle and booster doses Study Sample: 41,280 vaccine doses administered, divided among:
- Pfizer-BioNTech (Comirnaty): 57.5% of administrations
- Moderna (Spikevax): 33.4%
- AstraZeneca (Vaxzevria): 8.2%
- Johnson & Johnson (Jcovden): 0.8%
- Novavax (Nuvaxovid): 0.1%

Demographic Distribution: The sample analyzed in this study was heterogeneous based on sex and age, which was divided into 8 different age groups (18-29; 30-39; 40-49; 50-59; 60-69; 70-79; 80-89; >90).

Statistical Analysis: The statistical analysis was performed using STATA Software version 14.2, and evaluating all available data, the following analyses were conducted:

Descriptive Analysis

Classification of Adverse Reactions (ARs) by type (non-severe vs. severe) and by involved organ system (musculoskeletal, immune, gastrointestinal, etc.) Calculation of relative and absolute frequencies by sex, age, vaccine type, and administered dose. Analysis of ARs distribution among vaccines (Pfizer vs. Moderna, etc.) and among administered doses (first dose, second dose, etc.)

Inferential Statistics: The association between the main variables collected was measured. To compare frequencies, the Chi-square test or Fisher's Exact Test was used, depending on applicability, and the level of statistical significance was set at a p-value < 0.05 [9-15].

Statistical Evaluations: The results obtained from the analysis of this local sample were then compared with COVID-19 vaccine surveillance data published by AIFA in its Surveillance Report on COVID-19 vaccines (period 27/12/2020 - 26/12/2022, Report number 14) and with vaccine safety information monitored by EMA through the EudraVigilance system.

The comparison focused on the overall frequency of reports, severity, distribution by sex, dose, and type of adverse reaction, in order to highlight the alignment of local data with large-scale observations.

Results

During the time span to which the collected data refer (2020-2023), a total of 41.276 doses of COVID-19 vaccine were administered at the Military Polyclinic of Rome "Celio" [16-33].

The distribution of administered doses based on established age groups is visible in Table 1, where it can be noted that the highest number of doses, 11,750, of which 5,741 were male patients and 6,009 female patients, was administered in the 50-59 age group; followed by the 40-49 age group with a total of 10,825 doses, of which 5,238 were administered to male patients and 5,587 to female patients (Tab.1).

Table 1: Distribution of COVID-19 vaccine doses administered by age group and sex at the Military Polyclinic of Rome “Celio” (2020–2023).

Type \ Age	18–29	30–39	40–49	50–59	60–69	70–79	80–89	>90
Total by age	1235	4178	10825	11750	8852	2850	1570	20
Doses to male patients	538	1751	5238	5741	4573	1221	326	4
Doses to female patients	697	2427	5587	6009	4279	1629	1244	16

There was a certain uniformity in the distribution of doses based on sex, which was 47% in male patients and 53% in female patients.

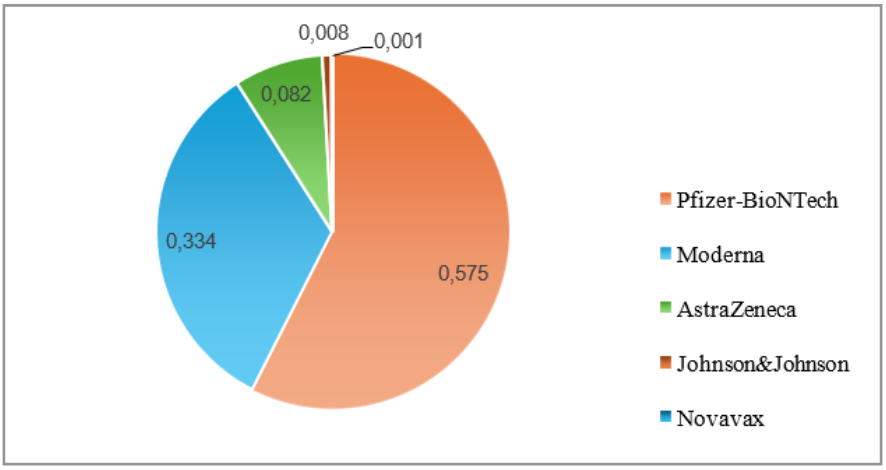


Figure 1: Percentage distribution of COVID-19 vaccine doses administered by vaccine type at the Military Polyclinic of Rome “Celio” (2020–2023).

The distribution of doses by vaccine type, in numerical terms, was as follows (Fig 1):

- Pfizer (PF): 23,739, equal to 57.5% of administered doses
- Moderna (MO): 13,780, equal to 33.4% of administered doses
- AstraZeneca (AZ): 3,385, equal to 8.2% of administered doses
- Johnson & Johnson (JJ): 330, equal to 0.8% of administered doses
- Novavax (NVX): 41, equal to 0.10% of administered doses

Regarding ARs, out of 41,276 administered doses, a total of 41 adverse reactions were recorded, corresponding to a reporting rate of 0.1% of the examined sample. Of these 41 adverse reactions, 3 (7.3%) were severe and 38 (92.7%) non-severe.

Table 2: Main demographic and clinical variables of subjects who experienced an adverse reaction

Demographic Variables	**n (number)**	**% (percentage)**	**Clinical Variables**	**n (number)**	**% (percentage)**
Age Group (years)			Adverse Reaction Type		
18–29	6	14,6	Severe	3	7,3
30–39	9	22	Non-severe	38	92,7
40–49	7	17,1			
50–59	8	19,5	Affected System		
60–69	5	12,2	Immune System	11	26,8
70–79	2	4,9	Skin and Appendages	5	12,2
80–89	2	4,9	Cardiovascular System	1	2,44
>90	2	4,9	Nervous System	4	9,8
			Musculoskeletal System	12	29,2
Age			Gastrointestinal System	2	4,9
Under 50	22	53,7	Respiratory System	1	2,44
Over 50	19	46,3	Psychological/Behavioral	4	9,8
Sex					
Dose Number					
Male	14	34,1	I	24	58,5
Female	27	65,9	II	12	29,3
			III	4	9,8
			IV	1	2,4
Vaccine Name					
Pfizer					
				12	29,3
			AstraZeneca	14	34,2
			Moderna	13	31,7
			J&J	1	2,4
			Novavax	1	2,4

* Percentages may not total 100 due to rounding

The ARs recorded in the sample examined mainly affected the districts and systems reported (Tab. 2), where it was possible to highlight a higher number affecting the musculoskeletal system (12 ARs, 29.2%) followed by reactions affecting the immune system (11 ARs, 26.8%) (Fig 2).

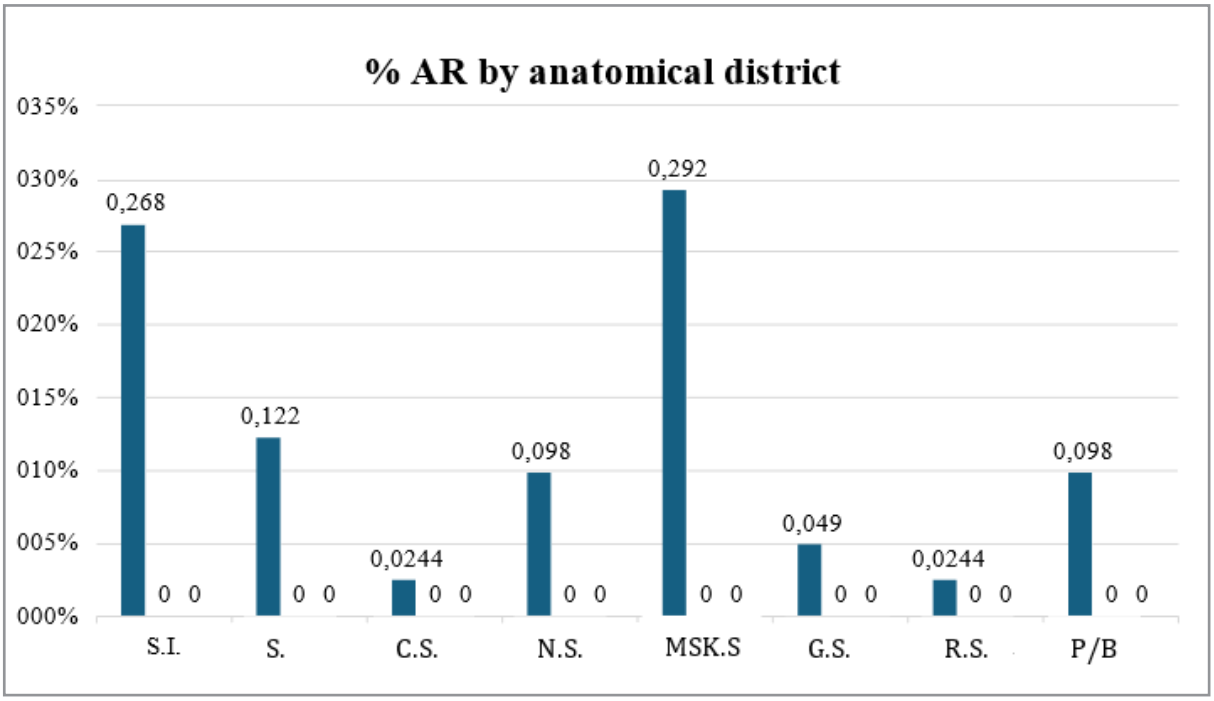


Figure 2: Percentage distribution of adverse reactions (AR) by anatomical district (S.I.= Immune System; S. = Skin; C.S. = Cardiovascular System; N.S.= Nervous System; MSK S.= Musculoskeletal System; G.S.= Gastrointestinal System; R.S.= Respiratory System; P/B= Psycho/Behavioral)

Regarding the frequency distribution of ARs based on sex and age, distinguishing severe from non-severe Ars (Tab.3), the highest number of ARs occurred in the female population included in the study with a total of 27 ARs (66%), of which 2 were severe, compared to 14 ARs (34%) that affected male patients, of which 1 was severe. Furthermore, severe reactions were recorded in the 30-39 age group, of which 1 male and 1 female, and another severe reaction occurred in a female patient belonging to the 40-49 age group.

Table 3: Adverse Reactions divided by age group and sex

Type \ Age	18–29	30–39	40–49	50–59	60–69	70–79	80–89	>90
Male ARs	1	1	2	4	2	1	1	1
Severe Male ARs		1						
Female ARs	5	6	4	4	3	1	1	1
Severe Femal ARs		1						

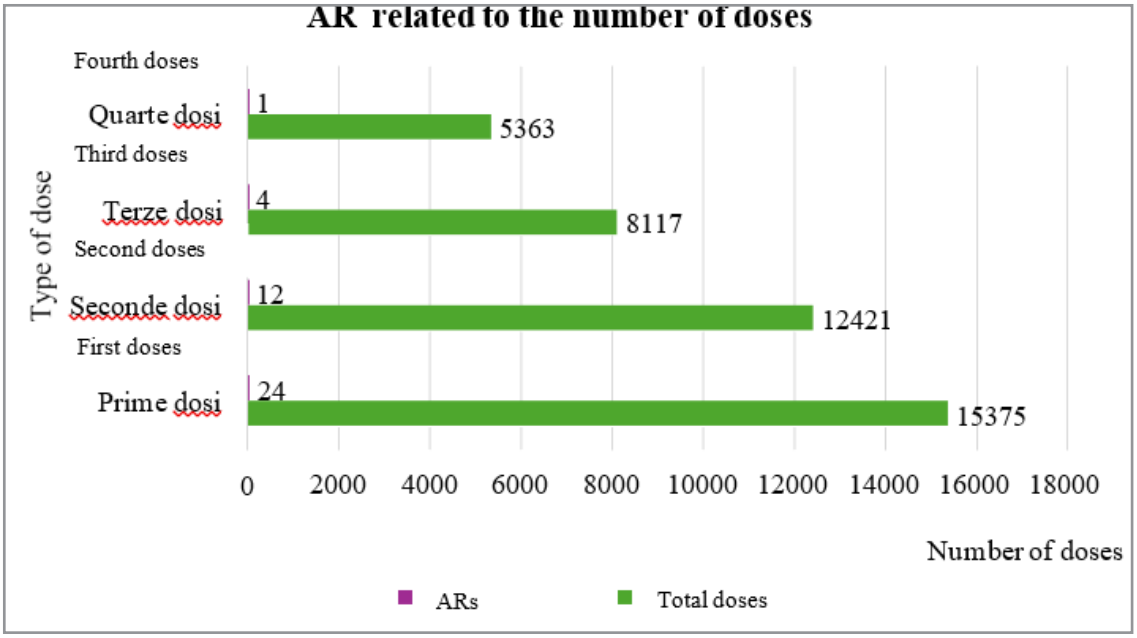


Figure 3: Correlation of the total 41 adverse reactions, divided by the type of doses administered

Analyzing the number of vaccinations divided by the number of doses (Fig.3) and correlating them to the reported ARs, we see that a total of 15,375 first doses were recorded, and of these, only in 24 cases (0.16%) did an AR occur; 12,421 were second doses with 12 ARs (0.10%); 8,117 were third doses with 4 ARs (0.05%); and 5,363 were fourth doses
with 1 AR (0.02%).

Regarding the correlation of ARs to the type of vaccine administered (Tab. 2), the highest number occurred with the AstraZeneca vaccine (14, 34.2%) followed by Moderna (13, 31.7%) and Pfizer (12, 29.3%) vaccines. The reported percentages refer to the total number of ARs; if instead we analyze these data by comparing the number of ARs to the number of doses administered by vaccine type, we obtain:

- Pfizer: Out of 23,739 doses administered, ARs occurred in 12 cases (0.05%)
- AstraZeneca: Out of 3,385 doses administered, ARs occurred in 14 cases (0.41%)
- Moderna: Out of 13,780 doses administered, ARs occurred in 13 cases (0.09%)

Therefore, the highest number of adverse reactions by vaccine type, correlating them to the number of doses administered, was with AstraZeneca, though still with very low values.

An inferential statistical evaluation was made by dividing the examined sample into two groups based on age, under and over 50 years, correlating ARs to the administration of the first and second doses, which are those for which a higher number of reactions were recorded (Fig 4).

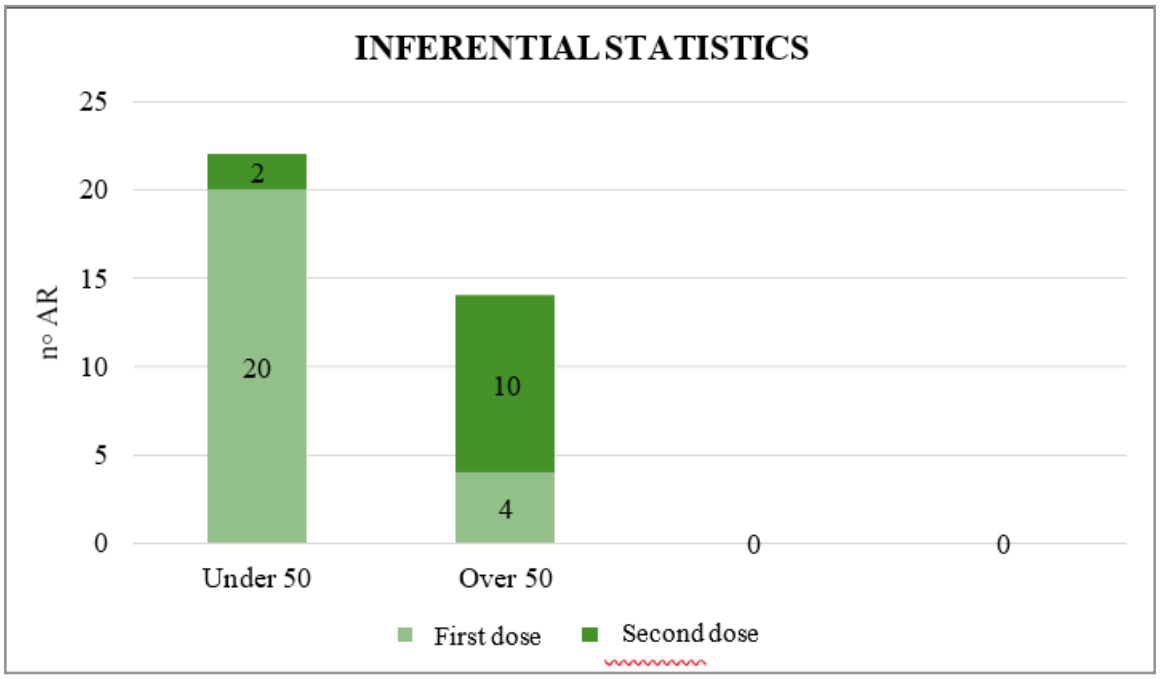


Figure 4: Inferential evaluation by dividing the sample into Under and Over 50 years old and correlating the relative ARs between the first and second doses

From the graph, it is possible to evaluate that an adverse reaction to the first dose affected 91% (n=20) of subjects under 50 years of age and 21% (n=4) of subjects over 50 years; this difference in percentage evaluated with Fisher's exact test with $p<0.001$ was statistically significant.

Regarding ARs to the second dose, 9% (n=2) were recorded for subjects under 50 years of age and 53% (n=10) for subjects over 50 years of age; in this case too, the difference was statistically significant with Fisher's exact test with $p=0.005$.

Statistical Evaluations and Direct Comparisons: Finally, a comparison was made between the data obtained in this study with AIFA (Italian Medicines Agency) data, which manages the National Pharmacovigilance Network (RNF), using as reference the Surveillance Report on COVID-19 vaccines (period 27/12/2020 - 26/12/2022, Report number 14) to see if the results obtained were in line with those at the national level. Regarding EMA (European Medicines Agency), this is a European agency responsible for approving vaccines that can be used in Europe and, together with national regulatory authorities (AIFA in Italy), monitors their safety through data collected by national agencies.

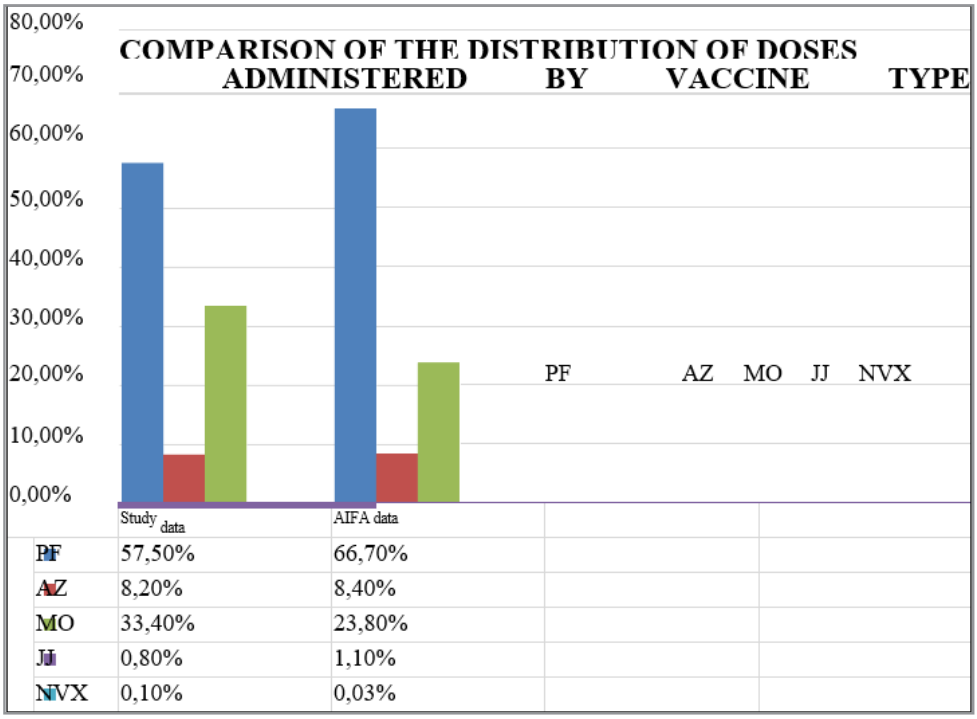


Figure 5: Comparison of the distribution of doses administered according to collected data and AIFA related data, categorized by vaccine type (PF=Pfizer; AZ=Astrazeneca; MO=Moderna; JJ=Johnson & Johnson; NVX=Novavax).

Dose Administration: the distribution of doses administered in the local context differs slightly from the national distribution (Fig. 5) particularly in the sample data analyzed, the distribution of Pfizer vaccine doses was slightly lower than the national one, while for Moderna vaccine doses it was slightly higher. For other types of vaccines, the values are quite similar.

Reporting Rates: Below is a direct comparison between the data from the analyzed sample and AIFA data regarding reporting rate and Confidence Interval:

Aifa Data

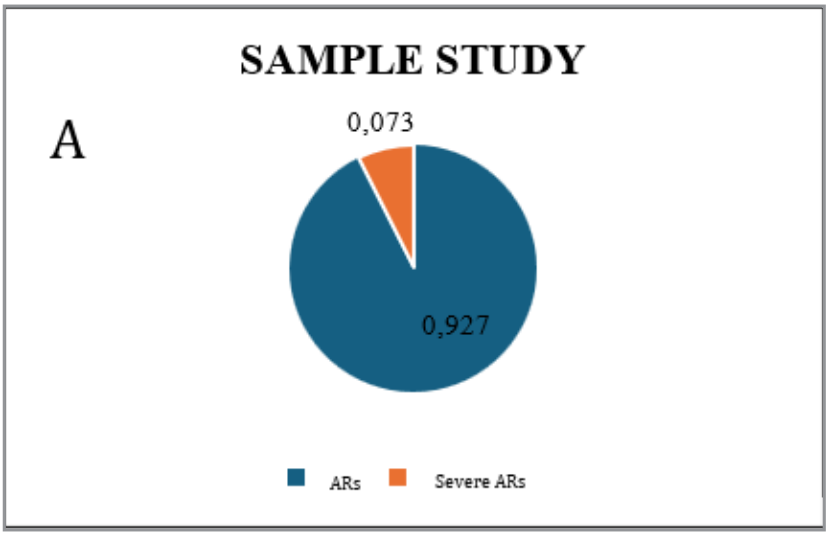
- 140,595 reports on 144,354,770 doses administered
- National overall reporting rate of 97 per 100,000 doses administered, or about 0.097%
- 95% Confidence Interval for the national rate is 96-98

Data from the Studied Sample:

- Regarding the data presented in this study in the time period from 2020 to 2023, a total of 41,276 vaccine doses were administered
- In the same period, 41 adverse reactions (AR) were recorded, corresponding to 0.1% of administered doses
- Converting this rate per 100,000 doses: (41 AR / 41,276 doses) * 100,000 ≈ 99.3 AR per 100,000 doses

The overall reporting rate observed in this study was 0.1% compared to 0.097%, with a minimal difference between the two, probably influenced in the first case by the reduced sample size compared to that of AIFA. Consequently, the Confidence Level of the study sample (about 99.3 per 100,000 doses) was very similar to the overall national one reported by AIFA (97 per 100,000 doses), thus falling exactly within the national confidence interval.

An additional comparison was also made in reference to ARs as visible from the comparison of the distributions below between the data reported in this study and national data (Fig.6) .



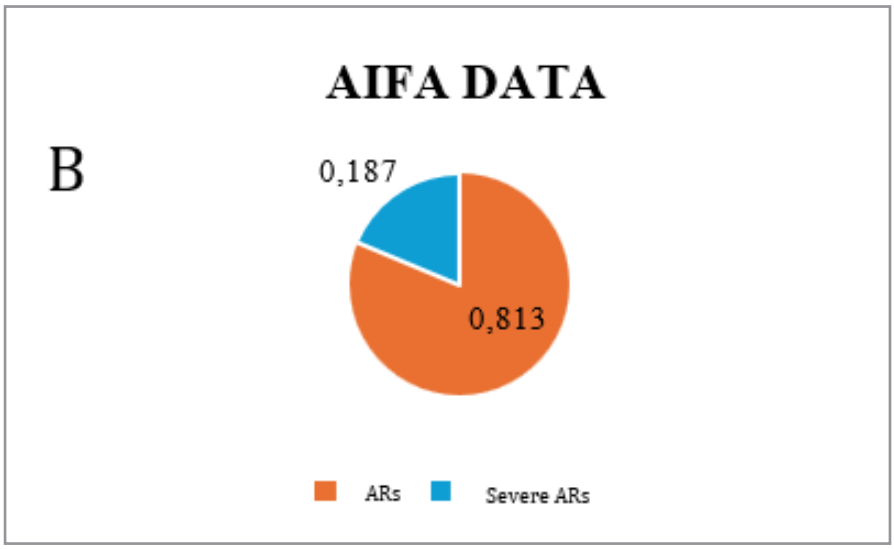
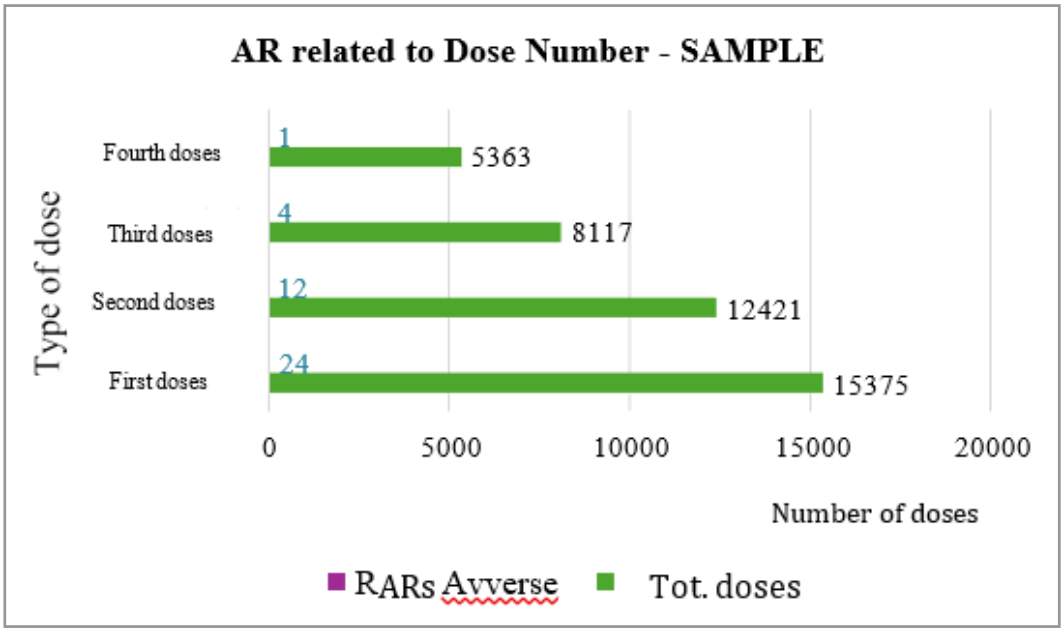


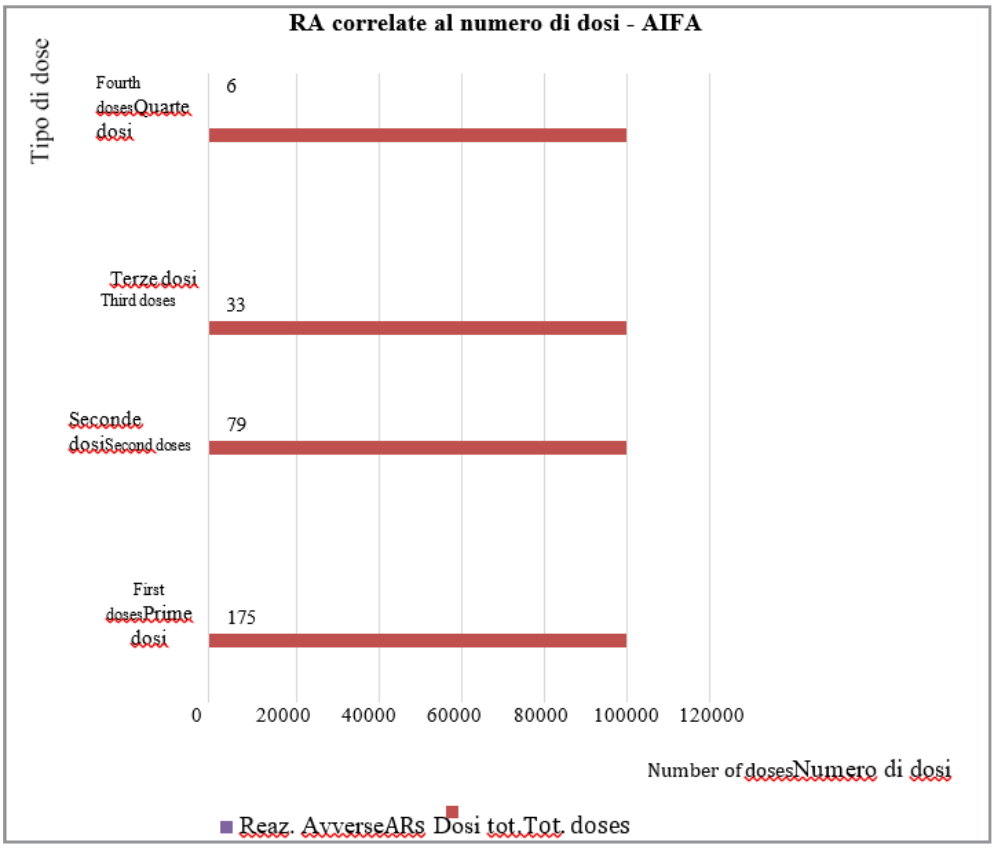
Figure 6: Percentage comparison of adverse reactions observed in the study sample (A) and the AIFA data (B)

In particular, at the national level, 26,305 severe ARs were reported, equal to 18.7%, corresponding to 18 severe events per 100,000 doses administered. The percentage of ARs classified as severe in the study of the sample analyzed in this study (7.3%) was significantly lower than the national data, but this may have depended on the specific characteristics of the population vaccinated at the Military Polyclinic, local reporting thresholds, or severity classification.

What emerges is that in the local sample, as at the national level, severe adverse reactions were significantly less frequent than non-severe ones.

ARs by Dose Number: Also, regarding the distribution of Adverse Reactions based on dose number, the data analyzed in this study indicate that most ARs occurred after the first dose followed in order by subsequent ones, reflecting the national trend as shown in graph (Fig. 6B).





Conclusions

The retrospective study conducted at the Military Polyclinic of Rome "Celio" confirms the high safety profile of COVID-19 vaccines administered between 2020 and 2023. Among

41,276 doses, 41 adverse reactions (0.1%) were recorded, aligning closely with the national rate reported by AIFA (0.097%). Most reactions (92.7%) were non-severe; severe events (7.3%) were rare and occurred mainly in individuals aged 30–49.

Adverse reactions primarily affected the musculoskeletal (29.2%) and immune systems (26.8%), with a greater incidence in female subjects (66%). The majority occurred after the first dose, consistent with national trends. Vaccine distribution showed minor local deviations from national averages, notably a slightly higher use of Moderna and lower of Pfizer.

Ongoing pharmacovigilance by AIFA and EMA continues to ensure safety, with no evidence to date of medium- or long-term risks. Current data supports the effectiveness and safety of vaccination in preventing severe disease, hospitalization, and death, especially in vulnerable populations. The benefits of COVID-19 vaccination clearly outweigh its risks.

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