SARS-CoV-2 vaccination patterns in a private hematology and internal medicine outpatient clinic

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Abstract

Objective. Determine the proportion of vaccinated patients in a private hematology and internal medicine outpatient clinic and potential factors in adherence in at-risk patients (due to onco-hematological diseases). **Materials and methods.** This is a cross-sectional study of outpatients from a private clinic. We applied a non-validated instrument to all patients attending the outpatient clinic from May to October 2021. According to the primary diagnosis, we classified patients into onco-hematological and non-onco-hematological patients. Since national authorities exclusively executed and planned the rollout of vaccines, the order and eligibility defined by authorities of vaccination was considered when conducting the analysis and patients were classified according to the their corresponding group. **Results.** 397 participants were accrued, 269 (68%) had an onco-hematological condition. In the whole group, 73 (18.3%) had a history of infection. Vaccination history was present in 286 persons (72%); 82%

Resumen

Objetivo. Determinar la proporción de pacientes vacunados en una clínica de hematología y medicina interna y los factores potenciales involucrados en la adherencia. **Material y métodos.** Estudio transversal en pacientes ambulatorios de una clínica privada. Se aplicó un instrumento no validado a todos los pacientes que acudieron a consulta externa de la clínica de mayo a octubre de 2021. De acuerdo con el diagnóstico primario, los pacientes se clasificaron como onco-hematológicos y no onco-hematológicos. Debido a que las autoridades nacionales ejecutaron y planearon exclusivamente la designación de vacunas, el orden y la selección de las mismas fue considerado al momento del análisis y clasificación de los pacientes de acuerdo con su grupo correspondiente. **Resultados.** Se reclutaron 397 participantes, 269 (68%) tenían una enfermedad oncohematológica y 73 (18.3%) tenían antecedente de infección. El antecedente de vacunación estuvo presente en 286 personas (72%), de ellas, 82% recibió

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had two doses. In the subset of 269 persons with an onco-hematological condition, 191 (71%) were vaccinated, whereas 95 participants with non-hematological conditions (73%) had received the vaccine. Vaccination status was associated with age (OR 1.07, 95%CI: 1.03,1.10, *p*<0.0001) and body mass index (OR 1.11, 95%CI: 1.04,1.17, *p*<0.0001). **Conclusions.** According to our study, vaccination adherence at our center is significantly different from the nationwide proportion of vaccines.

Keywords: vaccines; Covid-19; SARS-CoV-2; hematology; outpatients

dos dosis. En el grupo de pacientes con enfermedad oncohe-matológica, 191 (71%) habían sido vacunados, mientras que 95 participantes con otras afecciones (73%) habían recibido la vacuna. La vacunación se asoció con la edad (OR 1.07, IC95%: 1.03,1.10, *p*<0.0001) y el índice de masa corporal (OR 1.11, IC95%: 1.04,1.17, *p*<0.0001). **Conclusiones.** La adherencia a la vacuna en nuestro centro es significativamente diferente a la proporción de vacunación reportada por fuentes públicas.

Palabras clave: vacunas; Covid-19; SARS-CoV-2; hematología; pacientes ambulatorios

During the last 24 months, the Covid-19 pandemic claimed the lives of approximately four million people worldwide due to its rapid spread.[1] However, it is well-known that clinical manifestations and natural history are significantly heterogeneous, ranging from asymptomatic individuals to patients with severe pneumonia and multiple organ dysfunction.[2] For this reason, the pandemic drove several implications for patients with onco-hematological conditions, especially since hematological cancer and other similar diseases confer several immune abnormalities which ultimately result in higher morbidity and mortality rates;[3-5] thus, the development of any severe infection can impose a higher risk of adverse events in this context. Here, we present data of a cross-sectional study designed to explore the immunization patterns of persons attending an outpatient hematology and internal medicine private practice clinic, with and without onco-hematological conditions.

Materials and methods

Design

This study is a cross-sectional study of patients from the outpatient clinic at *Centro de Hematología y Medicina Interna* in Puebla, México, from May 2021 to October 2021. Although the study's main goal was to describe vaccine patterns in patients with and without onco-hematological conditions in a real-world background, we also assessed the adherence to Covid-19 vaccination in patients with onco-hematological and non-onco-hematological conditions as a proxy for the effectiveness of the national program in patients at-risk for Covid-19 related mortality and morbidity. In addition, differences between patterns of vaccination found in the clinic and those reported from public sources were sought. The nationwide vaccine administration rollout followed the order established in the National Policy for Vaccination issued by *Secretaría de Salud* (SS): 1) at-risk health person-

nel (December 2020-February 2021); 2) individuals aged 60 or more and other health personnel (February-May 2021); 3) people aged 50 to 59 years (May-June 2021) and pregnant women older than 18 years (May-June 2021), 4) individuals aged 40 to 49 years old (June-July 2021); and finally, 5) rest of population (July-March 2021).[6] Acute or chronic leukemia, lymphoma, multiple myeloma (and other plasma cell neoplasms), myelodysplastic syndromes, myeloproliferative neoplasia, anemia, thrombocytopenia, thrombophilia were categorized as onco-hematological conditions. Alkylating, antimetabolites, alkaloids, anthracyclines, and similar agents were classified as chemotherapy, while methotrexate, steroids, tacrolimus, ciclosporin, anti-thymocyte globulin, and other drugs with the same function were classified as immunosuppressors. Finally, agents such as lenalidomide, thalidomide, and monoclonal antibodies were classified as biological response modifiers (immunomodulators). Risk factors of severe infection and mortality related to Covid-19 defined by Centers for Disease Control and Prevention (CDC)[7] were recorded. The Institutional Review Board of *Clinica Ruiz* approved the study protocol, and all patients verbally agreed to participate before answering the survey.

Survey

The survey was applied to all patients prior to their scheduled appointment after obtaining their verbal consent. The development of the instrument considered the collection of data related to the previous history of SARS-CoV-2/Covid-19 and immunization details. However, the instrument relied only on self-reported data, and no proof of vaccination was used to confirm the vaccine status since the online system of government-issued certificates was not fully ready until July 2021 (two months after the start of this study). Therefore, a final survey with ten items was done: three affirmative and negative action (yes/no), two multiple-choice,

and five free text fields. The main objective of the survey was the collection of data about personal history of SARS-CoV-2 infection and, if affirmative, the severity, referred to as mild (general symptoms), moderate (oxygen requirement or hospitalization), and severe (intensive care therapy). Likewise, information was collected about the application of the SARS-CoV-2 vaccine, whether the application was made within the country or abroad—the type of vaccine they received, and whether their vaccination schedule was complete. We employed two vaccine doses as the criterion to define a complete scheme due to available scientific evidence during the study's design. In addition, the presence of adverse effects associated with vaccination.

Statistical analysis

Descriptive data are presented as median and interquartile ranges (IQR), while qualitative data are in frequencies and percentages (%). In order to identify a statistically significant difference of 10% in vaccine adherence from the nationwide proportion average in May 2021, we had to recruit a minimum of 205 participants to get a power of 80% and an alpha error of 5%. Alternative hypoth-

esis U-Mann-Whitney test and χ^2 were run to detect significant differences across groups (patients with and without onco-hematological conditions). We performed regression models for binary outcomes employing logistic regression to identify factors related to immunization adherence. Non-adjusted and adjusted odds ratio (OR) and their 95% confidence intervals (95%CI) were calculated as well. The adjustment of the regression model was conducted using the groups of vaccine rollout described early (every patient was classified into a particular group as stated by national authorities). To be considered statistically significant, the results should provide a two-sided *p*-value (*p*) less than 0.05.

Results

Features of the sample

Three hundred and ninety-seven participants were recruited for the study. Of these, 227 (57%) were female and 170 (43%) male. According to disease type, 269 (68%) had an onco-hematological condition, and 128 (32%) had a non-onco-hematological disease. Further characteristics are displayed in table I.[7]

Table I
MAIN FEATURES OF RECRUITED PARTICIPANTS. MEXICO, MAY-OCTOBER 2021

Feature		Hematological condition (n=269)	Non-hematological condition (n=128)	*p*
Age, years (IQR)		50 (33,65.5)	55.5 (43,68)	0.03*
Sex (%)	Female	149 (55)	78 (60)	0.296 (NS)
	Male	120 (45)	50 (40)	
BMI, kg/m² (IQR)		25.2 (22.2,28.6)	25.5 (22.6,29.4)	0.2287 (NS)
Risk factor‡ (%)	Any	122 (45)	79 (61)	0.002*
	No risk factor	147 (55)	49 (39)	
History of Covid-19 (%)	Never infected	217 (81)	107 (84)	0.482 (NS)
	Previously infected	52 (19)	21 (16)	
Group of vaccination (%)	First	3 (1)	0 (0)	0.166 (NS)
	Second	91 (34)	52 (40)	
	Third	46 (17)	27 (21)	
	Fourth	45 (16)	22 (18)	
	Fifth	84 (32)	27 (21)	
Recent or ongoing use of chemotherapy (%)	No	238 (88)	127 (99)	<0.0001§
	Yes	31 (12)	1 (1)	
Recent or ongoing use of immunosuppressants (%)	No	212 (78)	117 (91)	0.002*
	Yes	57 (22)	11 (9)	
Recent or ongoing use of immunomodulatory agents (%)	No	210 (78)	115 (90)	0.004*
	Yes	59 (22)	13 (10)	

IQR: interquartile ranges; BMI: body mass index; NS: not statistically significant; * p <0.05; ‡ Risk factors defined by the Center of Disease Control[7] (malignancy, chronic kidney disease, chronic liver disease, chronic pulmonary disease, cystic fibrosis, dementia, diabetes, heart conditions, hemoglobinopathy, HIV infection, immunocompromised state, obesity, history of bone marrow transplantation, stroke, tuberculosis); § *p* <0.0001

Covid-19 previous history

Of 397 patients included, 73 (18.3%) had a previous history of SARS-CoV-2 infection. Of them, 54 patients (73.9%) had a mild infection, 13 (17.8 %) had a moderate infection, and 4 (5.4%) suffered a severe infection; two patients experienced reinfection, which represents a reinfection rate of 2%.

Vaccine adherence

Vaccination history was recorded in 286 (72%) patients, of which 82% had a complete schedule, and three (1%) received an extra dose to their schedule. 50 (17%) of the patients received the vaccine outside the country, mainly in the United States. The mRNA-based Pfizer vaccine was the most frequent type of immunization, representing 56.4%, followed by AstraZeneca with 15.1% and Sinovac with 10.1% (figure 1). Regarding the vaccination adherence by age group, we observed that 89% of patients older than 60 years were vaccinated, 77% of patients between 50-59 years, 62% between the age of 49-40, and 24% of patients under 40 years of age have been vaccinated (figure 2). Of patients with an onco-hematological condition, 191 (71%) were vaccinated at the time of the survey, while 95 (73%) of participants with non-hematological conditions had received the vaccine. These proportions did not show any significant difference ($\chi 2$ 0.3; p 0.5). Regarding onco-hematological

patients, of 32 patients undergoing chemotherapy, 21 (65.6%) had been vaccinated; there were no significant differences ($\chi 2$ 0.7; p 0.3) in comparison with patients with no history of chemotherapy. Of 72 undergoing treatment with immunosuppressants, 48 (67.6%) received the vaccine with no significant differences in comparison with non-vaccinated patients with or without therapy with immunosuppressant drugs ($\chi 2$ 0.7; p 0.3). Of 72 patients using immunomodulatory agents, 57 (79.1%) reported having been vaccinated (figure 3), with no significant differences ($\chi 2$ 3.7; p 0.053) between the rates of immunomodulatory agents and vaccine status. The reinfection rate after immunization was 5 out of 286 (0.3%). There were no identifiable factors related to reinfection after Covid-19.

Factors related to vaccine adherence

Vaccine status at the time of completing the survey was associated with age (OR 1.07, 95%CI: 1.03,1.10, p<0.0001) after adjusting for the order groups of vaccination. Body mass index (BMI) showed a significant association (OR 1.09, 95%CI: 1.02,1.15, p<0.0001) with vaccine adherence after adjusting for the groups of vaccination. No association was found for sex, onco-hematological condition, previous Covid-19 infection, recent or ongoing exposure to chemotherapy, immunosuppressants, or immunomodulatory agents (table II). Vaccine adherence overseas was studied as well, being age (OR 1.07,
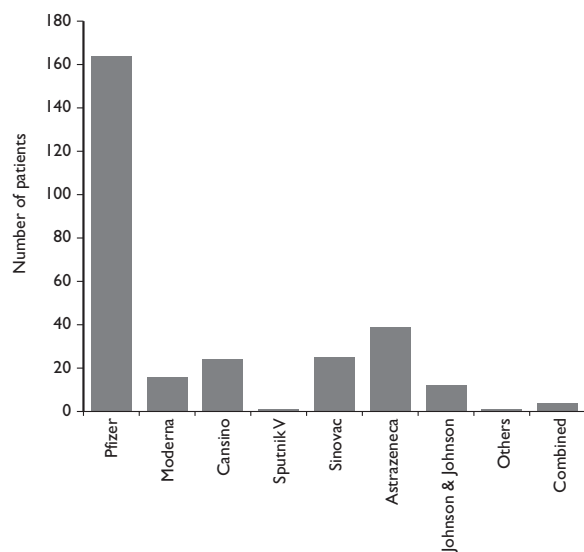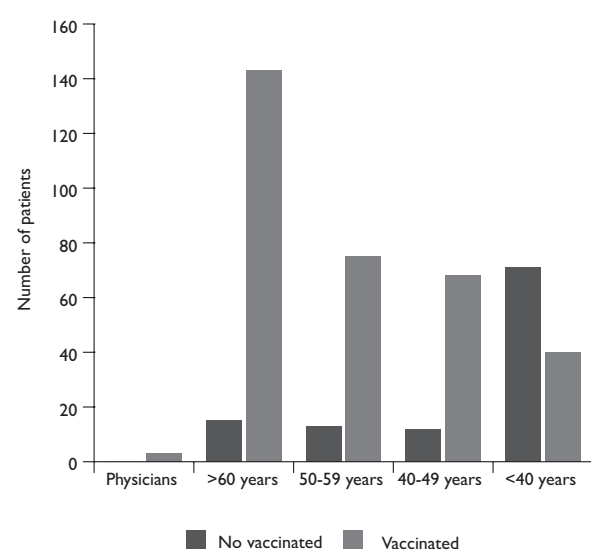
95%CI: 1.02,1.13, p 0.003) and female sex (OR 2.6; 95%CI 1.3,5.1; p 0.004). No other features were associated with vaccine adherence outside Mexico after adjustment for the groups of vaccination.

Discussion

According to a widespread global data observatory, it is estimated that by November 2021, 51.7% of the world population will have received at least one dose of the Covid-19 vaccine, and 7.4 billion doses have been administered worldwide.[8] In the cohort that we are informing, a more significant proportion of people have received at least one dose, representing almost 25% higher than the general population. It must be mentioned that, since our cohort stems from a private practice clinic, a selection bias may be present, not reflecting the socioeconomic conditions of the inhabitants of the country. México has a lower overall rate of vaccination (49% one dose) in comparison to countries with a similar gross domestic product, such as Colombia (53%), Brazil (60%), Argentina (66%), Uruguay (78%) or Chile (81%).[8]

In addition to a higher proportion of vaccination rates in the entire sample, we observed a more significant proportion of vaccine adherence in patients of older age, which is directly related to the vaccination calendar established by the government of Mexico, which distributed the rollout as follows: December-February 2021 for health personnel on the first line
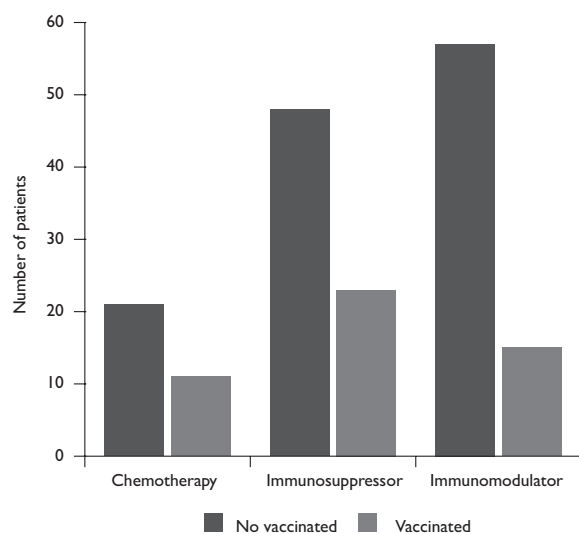
of attention to Covid-19, February-May for people aged 60 or over more years and other health personnel, May-June for people from 50 to 59 years old, pregnant women aged 18 and over from the third month of pregnancy, June-July for people from 40 to 49 years old and finally from July-March of 2022 for the rest of the population.[6] Interestingly, increased age was found to be a significant factor in following preventive measures for Covid-19 among people from Central México;[9] this observation may be related to higher adherence and acceptability to vaccination in the Mexican population.

Furthermore, the odds for vaccine adherence were higher in people for every unit increase of BMI independently of the group of vaccination and age, which is one the most critical risk factors proposed by the CDC to develop severe Covid-19. This finding may suggest that the availability and acceptability of vaccination in some individuals could be broader or more effective. However, additional studies, including other factors related to adherence and acceptability[10] should be carried out to define the role of diffusion and communication of health policies and recommendations in patients with higher risk for morbidity- and mortality-related Covid-19.[11]

Our study also found that patients with ongoing or recent exposure to chemotherapy, immunosuppressants, or immunomodulatory agents had vaccination rates of 65, 67, and 79%, respectively. However, it is essential to note that 20 to 35% of patients have not yet received a vaccine dose; given the high risk of severe Covid-19 and mortality in this group, additional measures should be taken to increase protection in at-risk patients.[12-14] Is vital to state that our sample may contain people with higher access to healthcare since they were enrolled in a private clinic and vaccination overseas was considerably high. This finding should be considered since socioeconomic inequalities are a substantial factor in adverse outcomes in Covid-19 in many countries, including Mexico.[15] Furthermore, according to a cohort with hematological malignancies,[16] the hospitalization rate was 10% in comparison with <1% for another type of malignancies (other groups with a higher risk in comparison with the general population) in the same geographical location.[17] Therefore, the increase in mortality related to Covid-19 in cancer patients and specifically in hematological malignances and related diseases has highlighted the importance of vaccination in this group.[18]

These observations are valuable since rollout strategies should be actively revised to timely administer boosters and manage immunization status for at-risk patients. This strategy could have tremendous usefulness, primarily due to the need for further immunizations are needed for special populations[19] and the rise of emergent variants such as the B.1.1.529 (Omicron) variant[20] and

future variants that could compromise the current efforts made by the public and private institutions on the rollout of vaccines. For instance, at our center, patients with onco-hematological diseases represented 68% of the whole sample, and almost 50% of patients had at least one risk factor as defined by the CDC. These figures represent a high proportion of patients in need of further immunizations, and while more months elapse, their risk for complications may sustain.

Two main reasons limit this study: in the first place, the use of a non-validated survey to self-report as a proxy for vaccine adherence. While certificates and other proofs of vaccination are more precise, the unavailability of those resources in Mexico was significantly limited during the first 24 months of the pandemic. Nevertheless, using such documents could reduce our study's classification and self-selection bias, mainly regarding vaccine adherence, type, and application dates. Moreover, a similar issue could improve the reporting of Covid-19-related data. In addition, since data from public sources is sparse and not unified, our country's vaccination rates may not be entirely precise.

Future studies must address these limitations and provide data related to factors that may limit or modify the adherence and acceptability of the vaccine taking into consideration at least the following areas: healthcare provider center (public versus private, specialized versus non-specialized, etc.), unique features (socioeconomic status, education levels, occupation, etc.) and disease-specific characteristics (type of condition, therapies, etc.). Another research opportunity is to characterize outpatient settings regarding modifications of treatments using chemotherapy[21] or immunomodulatory/immunosuppressive agents[22] during and after vaccination and their efficacy on disease-specific outcomes. Once knowing factors related to adherence and acceptability, further immunization and booster rollout campaigns may be customized to address at-risk patients.

Vaccine adherence at our center is significantly higher than reported at nationwide official reports. This could be led because patients in our sample may have more comprehensive healthcare access due to many unknown factors. Older patients and those with higher BMI had significantly more adherence to vaccination than others. These factors could be of paramount relevance since advanced age and obesity are two important risk factors for developing moderate to severe Covid-19. In addition, the proportion of patients vaccinated overseas represented a significant proportion of vaccine adherence among all patients. Although these observations were conducted in a single private center in México, these findings may support programs of rollout and communication strategies for at-risk

patients, for instance, those with onco-hematological conditions. Additional studies are needed to support these results, exploring healthcare-, individual-, and socioeconomic-related data.

Declaration of conflict of interests. The authors declare that they have no conflict of interests.

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