

SHORT REPORT

SARS-CoV-2 infection and vaccination in patients with hairy-cell leukaemia

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Funding information

Associazione Italiana per la Ricerca sul Cancro - Grant "5 per mille" to E.T. and B.F., Grant/Award Number: 21198

Summary

Little is known of the course of COVID-19 and the antibody response to infection or vaccination in patients with hairy-cell leukaemia (HCL). Among a total of 58 HCL cases we studied in these regards, 37 unvaccinated patients, mostly enjoying a relatively long period free from anti-leukaemic treatment, developed COVID-19 between March 2020 and December 2021 with a usually favourable outcome (fatality rate: 5/37, 14%); however, active leukaemia, older age and more comorbidities were associated with a worse course. Postinfection ($n = 11$ cases) and postvaccination ($n = 28$) seroconversion consistently developed, except after recent anti-CD20 or venetoclax therapy, correlating with perivaccine B-cell count. Vaccination appeared to protect from severe COVID-19 in 11 patients with breakthrough infection.

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KEY WORDS

anti-SARS-CoV-2 vaccination, COVID-19, hairy-cell leukaemia, post-COVID-19 seroconversion

INTRODUCTION

Hairy-cell leukaemia (HCL) is a rare B-cell neoplasm treated with myelotoxic and immune-suppressive chemotherapy and/or anti-CD20 immunotherapy.¹ Little is known about COVID-19 outcome in HCL patients and on their antibody response to infection or vaccination. In particular, the only published cohort study focusing on HCL ($n = 40$ patients) recently reported a largely severe (48% of cases) or critical (35%) disease course, with 10 deaths (including nine COVID-19-related) in 35 unvaccinated cases (29%) and none in five vaccinated patients.² Herein, we describe a larger HCL cohort (58 patients in total) not only for COVID-19 outcome in unvaccinated and vaccinated cases, but also for seroconversion post infection and post vaccination.

METHODS

Seventeen Italian centres participating in the retrospective and prospective IRB-approved ITA-HEMA-COV study on COVID-19 in haematologic malignancies (including written or verbal informed consent)³ provided clinico-laboratory data on a total of 58 HCL patients: (i) with SARS-CoV-2 infection microbiologically confirmed in a pharyngeal swab between March 2020 and April 2022; and/or (ii) with quantitative anti-SARS-CoV-2 serology (units/ml) performed post COVID-19 and/or post vaccination through a variety of different, largely anti-spike, assays. In particular, 48

patients could be analysed for: (a) COVID-19 outcome without prior vaccination in 37/48 cases (Figure 1, left branch); (b) seroconversion post vaccination (Figure 1, central box at the bottom) in the other 11/48 cases without history of prior COVID-19 (Figure 1, right branch), as well as in 17 of the 37 cases with prior COVID-19 (Figure 1, yellow ovals), for a total of 28 cases with available serology data after vaccination; and (c) seroconversion after infection in 11 of the 37 cases with prior COVID-19 who had these data available for analysis (Figure 1 green oval). The remaining 10/58 HCL patients (Figure 1, middle branch) were instead selected *ad hoc* for a history of COVID-19 post vaccination to describe the disease course in the setting of previous vaccination, together with one of the 11 vaccinated cases of point b above (Figure 1, right branch) who developed COVID-19 after being tested for postvaccination seroconversion.

COVID-19 severity was graded as per China Centers for Disease Control and Prevention definitions.⁴

COVID-19 in unvaccinated patients

Thirty-seven patients (M:F = 32:5; median age: 58 years; median Charlson Comorbidity Index (CCI) 3; Table 1) developed COVID-19 during the following pandemic periods: March 2020–June 2020, $n = 7$; October 2020–April 2021, $n = 27$; July 2021–December 2021, $n = 3$.

In 30/37 cases (81%), HCL diagnosis was already known since a median of 92 months pre COVID-19 (range 6–429),

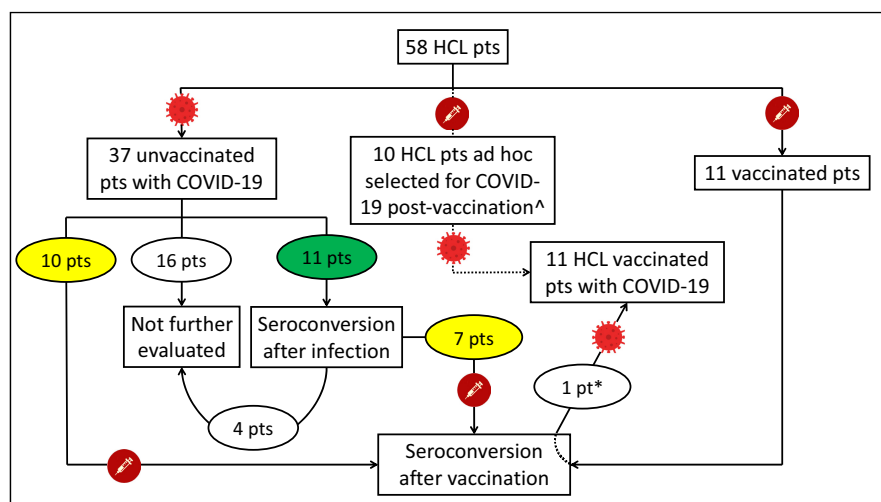




FIGURE 1 Study flow chart. , Vaccination against SARS-CoV-2; , SARS-CoV-2 infection. *This vaccinated patient was tested for seroconversion before developing COVID-19. ^These 10 patients were selected *ad hoc* for a history of COVID-19 post vaccination (i.e., we cannot provide a denominator for this analysis), whereas the 11 vaccinated patients to the right were part of a systematic data collection effort (like the 37 unvaccinated COVID-19-positive patients to the left) and one of them (1/11) later developed COVID-19. HCL, hairy-cell leukaemia. Pt(s), patient(s).

TABLE 1 Characteristics of unvaccinated HCL patients with COVID-19 ($n = 37^a$).

	Number
Patient characteristics	
Male	32
Female	5
Median age in years (range)	58 (33–85)
Median Charlson Comorbidity Index (range), $n = 36$ pts	3 (2–12)
Period of COVID-19 diagnosis	
March 2020–June 2020	7
October 2020–April 2021	27
August 2021–December 2021	3
Previous therapies	
None	10
Newly diagnosed	7
In a watch-and-wait program	3
Purine analogs	26 ^b
Anti-CD20 monoclonal antibodies-based treatments	
RTX monotherapy	2
OBI monotherapy	2
RTX + Vemu	1
RTX; RTX + 2CDA	1
RTX; Vemu + RTX	1
OBI; Vemu + OBI	1
RTX; OBI; Vemu + OBI	1
2-CDA+RTX; OBI; Vemu + OBI	1
Other treatments	
Interferon	3
Vemu monotherapy	2
Splenectomy	1
Moxetumomab–pasudotox	1
Median months from last therapy (range), $n = 27$ pts	29 (1–272)
Median months from last purine analog (range), $n = 26$ pts	61 (5–272)
Median months from last anti-CD20 antibody dose (range), $n = 10$ pts	32 (1–139)
COVID-19 severity	
Mild	22 (59%)
Severe	10 (27%)
Critical	5 (14%)
COVID-19 fatality rate by period of diagnosis	
March 2020–June 2020	1/7 (14%)
October 2020–April 2021	4/27 (15%)
August 2021–December 2021	0/3 (0%)
Median values of hematologic^c and immunologic^d parameters (range)	
Haemoglobin in g/L, $n = 36$ pts	133 (73–173)
Platelets/mm ³	138 000 (25 000–205 000)

(Continues)

TABLE 1 (Continued)

	Number
Leukocytes/mm ³ , $n = 36$ pts	3650 (300–8210)
Neutrophils/mm ³	1920 (200–5747)
Lymphocytes/mm ³ , $n = 35$ pts	1015 (0–3100)
Monocytes/mm ³ , $n = 24$ pts	226 (10–1067)
IgG mg/dl, $n = 19$ pts	942 (432–1371)
IgA mg/dl, $n = 18$ pts	173 (50–1660)
IgM mg/dl, $n = 18$ pts	59 (7–955)
B cells/mm ³ , $n = 18$ pts	79 (0–411)
Total (CD3+) T cells/mm ³ , $n = 16$ pts	679 (373–2338)
CD4+ T cells/mm ³ , $n = 15$ pts	383 (189–975)
CD8+ T cells/mm ³ , $n = 15$ pts	338 (79–1169)
NK cells/mm ³ , $n = 15$ pts	165 (52–835)

Abbreviations: 2-CDA, cladribine; NK, natural killer; OBI, obinutuzumab; RTX, rituximab; Vemu, vemurafenib.

^aAll data refer to 37 patients (pts), except where otherwise noted.

^b2-CDA in 19 patients, 2-CDA and pentostatin at different times in 5 patients, pentostatin in 2 patients.

^cHaematological parameters were evaluated at a median of 2.75 months (range 0.5–10) before COVID-19 diagnosis ($n = 26$ cases), or at COVID-19 in the remaining 11 cases without a previous recent exam.

^dData on total serum immunoglobulins and blood lymphocyte subpopulations were respectively available in up to 19/37 patients (51%) and 18/37 patients (49%) at a median of respectively 3 and 17.5 months before COVID-19 diagnosis (range 0–187 and 1–172), and showed mild reduction of total and CD4+ T cells and values toward the lower normal limit for B cells and IgM, possibly reflecting the T-cell- and B-cell-depleting effect of previous purine analogs and anti-CD20 antibodies, respectively.

whereas in 7/37 patients (19%) HCL was diagnosed in the context of COVID-19. A median of one anti-leukaemic therapy (range 1–16) was delivered in 27 cases a median of 29 months earlier (range 1–272) (Table 1); treatment was ongoing in a single case, with rituximab.

Blood counts close to COVID-19 diagnosis showed normal median values except for mild lymphopenia (1015/mm³) and thrombocytopenia (138 000/mm³) (Table 1). Indeed, 28/37 patients (76%) did not have active leukaemia causing cytopenia(s) (neutrophils <1000/mm³, haemoglobin <100 g/L or platelets <100 000/mm³), whereas 9/37 cases (24%) had cytopenia(s), including all seven newly diagnosed.

Despite no patients having received specific direct anti-SARS-CoV-2 drugs (monoclonal antibodies or viral enzyme inhibitors), COVID-19 was mild in most cases (22/37, 59%), severe in 10/37 (27%) and critical in 5/37 (14%). Five patients (14%; critical, $n = 4$; severe, $n = 1$) died of COVID-19 (one in March 2020, four in October–November 2020), while 32 survived and recovered (completely, $n = 31/32$; unknown, $n = 1/32$).

The five dead patients had active leukaemia (newly diagnosed, $n = 2$; under treatment $n = 1$; age 51–59–69 years and CCI 3–5–4 respectively), or did not have cytopenias ($n = 2$) but were relatively old (68 and 75 years) and had more comorbidities (CCI 6 and 8, respectively). Indeed, active leukaemia appeared enriched among dead cases (3/5, 60%) versus survivors (6/32, 19%) (p value: 0.081, approaching significance

despite the low death rate). The six cases with active leukaemia surviving COVID-19 (mild, $n = 3$; severe, $n = 3$) were relatively young (41–63 years) and had few comorbidities (CCI 2–4). Consistently, age and CCI were higher in non-mild (fatal, critical or severe) COVID-19 cases ($n = 15$: median age 63 years, median CCI 4) compared to mild ones ($n = 22$: median age 55 years, median CCI 3; p value: 0.012 and 0.061, respectively). Conversely, no significant association emerged between COVID-19 severity (mild vs. non-mild) and sex (p value: 0.63) or time from last therapy (median 35 and 22 months, respectively, in 18 and nine previously treated cases, respectively; p value: 0.37), although we note that the only patient recently treated (≤ 3 months earlier; a 69-year-old male with CCI 4 under ongoing rituximab) died of COVID-19.

Whereas the associations we observed in HCL between COVID-19 course and clinical variables like age, comorbidities and disease status are broadly similar to those observed in other haematological malignancies,^{3,5,6} including chronic lymphocytic leukaemia (CLL),⁷ the HCL cohort reported by Lamure et al.² showed, compared to ours, higher rates of non-mild COVID-19 (83%, 33/40 patients, including five previously vaccinated) and death (29%; 10/35 cases), despite a median age (60 years) and comorbidity rate (33%) similar to ours (58 years and 35%, respectively). Reasons underlying this discrepancy might include: shorter time from HCL diagnosis to COVID-19 in their cohort (median 14 months,² vs. 92 in ours); likely shorter time from last anti-leukaemic treatment in their series (median 3 months in the only 13/40 patients with these data²) versus ours (median 29 months); and fewer patients in remission or with untreated stable disease in their versus our cohort (respectively 26/40, 65%²; and 28/37, 76%).

Antibody response to COVID-19

Anti-SARS-CoV-2 serology post infection (and pre vaccination) was performed in 11/32 COVID-19 survivors (Figure 1). All cases but one showed an antibody response, robust in two cases (236 and 62 500-fold over the positivity threshold (FOPT); assessed after 4.5 and 5.5 months) and mild/moderate in eight cases (2.7–8.9 FOPT, assessed after 1.5–12 months).

No associations emerged between serological response occurrence or strength and HCL status at COVID-19 (active disease, $n = 3$; remission, $n = 8$), COVID-19 severity (mild, $n = 5$; severe, $n = 6$), or time between COVID-19 and serology (not shown), while we could not evaluate the effect of last anti-leukaemic therapy as it was delivered recently to only one patient (5 months earlier, with cladribine; vs. 11–116 months in the other seven previously treated cases).

The seroconversion rate observed in HCL cases (10/11, 91%) seems greater than in other haematological malignancies (164/237, 69%,⁸ although statistical significance is not reached— p 0.18—perhaps due to the low number of HCL cases), possibly due to the high efficacy of anti-HCL

therapies allowing long treatment-free intervals for immunological reconstitution.

Antibody response to vaccination

Antibody response to vaccination was evaluated in 28 HCL patients after one or more vaccine dose (mRNA-based BNT162b2 or mRNA-1273, $n = 27$; vector-based ChAdOx1-S, $n = 1$), comprising 17 cases with and 11 without previous COVID-19 (Figure 1).

The former 17 patients (of whom 12 previously treated, a median of 36 months before vaccination; range 12–278), included seven cases who had been evaluated for seroconversion after 1.5–12 months following infection and who later received 1–3 vaccine doses 1.5–16 months after first serology; upon serology repetition 1.5–5.5 months following the last vaccine dose, six of these seven cases enhanced their antibody response 5.6–772-fold over the first test, and the remaining one maintained an already high titre (FOPT: 236 prevaccination, 209-fold postvaccination). The other 10/17 patients with previous COVID-19, but without prevaccine serology, also received 1–3 doses and, 0.5–6 months later, all responded to an extent (median: 115 FOPT; range 6.2–800) larger than the 11 COVID-19+ cases evaluated postinfection/prevaccination (p value: 0.013), suggesting vaccine-induced enhancement of antibody response also in such 10 COVID-19-positive cases without prevaccine serology. In neither subset of these 17 patients an association emerged between antibody levels post vaccination and vaccine dose number (not shown).

The 11/28 patients without known history of prior COVID-19 all received anti-leukaemic treatment(s) pre vaccination, recently ($n = 6/11$; 0.7–6 months earlier) or more remotely ($n = 5/11$; 37–69 months earlier): 8/11 cases (73%) showed an antibody response (0.7–2.5 months after two doses) of variable magnitude (3.4–107.1 FOPT; not apparently correlating with time from last treatment—not shown), whereas 3/11 patients (27%) did not seroconvert 1–1.5–1 months after 3–2–2 BNT162b2 doses, respectively. These three patients recently received anti-CD20 immunotherapy ($n = 2$; until 2–3 months pre vaccination) or venetoclax ($n = 1$; until 20 days pre vaccination), consistent with the impaired serological response to vaccination reported for these treatments in other diseases.^{9–12} Conversely, none of the eight seroconverters received venetoclax or recent anti-CD20 therapy (p value: 0.0061; 4/8 cases did receive anti-CD20 antibodies, but four or more years earlier).

Indeed, in a flow-cytometry analysis of blood B cells that was performed in 11 presumable vaccine responders (five without and six with prior COVID-19) sufficiently near the first vaccine dose (median of 8.5 months before or after; range 0–18.5) to be unaffected by last anti-leukaemic therapy (completed a median of 38 months earlier, range 20–278), the B-cell count (median 149/mm³, range 13–496/mm³) was greater than in the 2/3 non-responders evaluable in this

regard (0 and 7 B cells/mm³ at 5.5 and 7.5 months after the first vaccine dose; *p* value: 0.026). No correlation emerged between B-cell numbers and antibody levels (*r* = -0.147; *p* value: 0.65).

Overall, 25/28 HCL patients (89%) likely had a serological response post vaccination, a rate similar to that in other mature B-cell neoplasms not recently treated.^{9,10,12,13}

COVID-19 in vaccinated patients

Finally, between November-2021 and April-2022 (a period largely dominated by the omicron viral variant in Italy), 11 patients (nine males) without prior COVID-19 got infected by SARS-CoV-2 0.7–8 months after vaccination with two doses (BNT162b2, *n* = 5; ChAdOx1-S, *n* = 1) or three doses (BNT162b2, *n* = 4; unknown, *n* = 1). Whereas their age and comorbidity load were similar to those of the unvaccinated cases (median 62 vs. 58 years, respectively; *p* value: 0.27; median CCI 4 vs. 3, respectively; *p* value: 0.97), vaccinated cases were enriched (7/11, 64%, vs. 9/37, 24% in unvaccinated cases; *p* value: 0.027) for unfavourable HCL characteristics at COVID-19 diagnosis, that is, active leukaemia (*n* = 3 cases) and/or anti-leukaemic treatment that was ongoing (*n* = 2 cases; venetoclax + rituximab and vemurafenib + cobimetinib) or was recently completed (≤3 months earlier, *n* = 3 cases: cladribine, *n* = 2; cladribine+rituximab, *n* = 1).

Yet, COVID-19 was severe in only 2/11 vaccinated cases (18%), and mild or even asymptomatic in 9/11 (82%); the latter included almost all patients (6/7) having the above unfavourable HCL characteristics and all three cases receiving specific anti-SARS-CoV-2 therapy (bamlanivimab/etesivimab, *n* = 1; sotrovimab + molnupiravir, *n* = 1; nirmatrelvir/ritonavir, *n* = 1). No vaccinated patient had critical or fatal COVID-19 or required invasive ventilation, whereas such instances were numerically higher among unvaccinated patients (*n* = 8/37, 22%; *p* value: 0.170).

Hence, consistent with other haematological malignancies,¹⁴ COVID-19 severity might have been mitigated by vaccination in our HCL patients, possibly together with specific anti-viral therapies as well as improved knowledge and clinical management of COVID-19 over time.

CONCLUSIONS

In conclusion, the course of COVID-19 was usually favourable in this cohort of unvaccinated HCL patients mostly enjoying a relatively long time from last anti-leukaemic treatment; however, active leukaemia, older age and more comorbidities seemed to increase the severity and/or fatality of COVID-19. Antibody response to infection and vaccination consistently developed in HCL patients, except after recent anti-CD20 or venetoclax therapy, and correlated with perivaccine blood B-cell count. Vaccination appeared to associate with milder COVID-19.

AUTHOR CONTRIBUTIONS

Enrico Tiacci contributed to conception and design of this study on HCL patients. Francesco Passamonti and Paolo Corradini are the principal investigators of the general ITA-HEMA-COV study of COVID-19 in haematological malignancies. Enrico Tiacci and Alessandro Mancini contributed to acquisition, analysis and interpretation of data and wrote the paper. All authors recruited participants, collected data and helped in critical revision of the manuscript. All authors read and approved the final manuscript.

ACKNOWLEDGEMENTS

Enrico Tiacci and Brunangelo Falini acknowledge the support of AIRC (Italian Association for Cancer Research) Grant “Metastasis/5-per-mille” no. 21198. We thank Dr Valeria Cardinali for help in filling the Case Report Forms of a few patients.









CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest that are relevant to this report.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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How to cite this article: Tiaci E, Mancini A, Marchetti M, D’Elia GM, Candoni A, Morotti A, et al. SARS-CoV-2 infection and vaccination in patients with hairy-cell leukaemia. *Br J Haematol*. 2023;201:411–416. <https://doi.org/10.1111/bjh.18606>