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Characteristics of patients diagnosed for acute myeloid leukemia before and during the 2020 COVID-19 pandemic: the DATAML population-based cohort.

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Abstract

Literature shows heterogeneous impact of recommendations to deal with sars-cov-2 infection on AML management during the 2020 Covid-19 pandemic. Available French data only rely on monocentric observations or simulations. From the DATAML cohort, including all AML patients cared for in the centers of South-West France, we compared the characteristics of patients diagnosed in two periods: 2020 and 2015-2019. We use time series approach to describe the monthly proportion of patients with extreme values on hemoglobin, white blood cells, platelets, and blasts counts, as well as early deaths. We found a slight impact of the first lockdown on hemoglobin and platelets, with statistical significance reached only for platelets distribution gap between the two periods. Similar but less marked patterns were found for WBC and blood blasts. These did not translate in terms of early deaths, which was considered to be likely due to a favorable local conjuncture associating a moderate incidence of sars-cov-2 and the absence of bed closing in onco-hematology or ICU dedicated to hematology in any centers providing intensive care for AML patients. Yet, our results might still be seen as an insight of what would have happened in less favorable contexts.

Keywords: Covid-19, Acute Myeloid Leukemia, observational cohort, temporal variations, AML characteristics at diagnosis

Introduction

To deal with the vulnerability of cancer patients to sars-cov-2 infection, the international community has recommended substantial adaptations in both the organization of care and standards of management to preserve care continuity and account for the risk of sars-cov-2 infection in the benefit-risk balance assessment for treatment delivery (1, 2). For acute myeloid leukemia (AML), generally considered an oncological emergency, the recommendation included (1) screening for Sars-CoV-2 infection prior to chemotherapy; (2) wait for cytogenetics and molecular biology before starting treatment; (3) allow omission of a consolidation cycle in the presence of measurable/minimal-negative residual disease; (4) favor the "3+7" induction regimen and reduced cytarabine (1. 5 rather than 3 g/m²) consolidation for patients fit for intensive chemotherapy, and for unfit patients, less intensive drug regimens or palliative care; and finally, (5) defer elective allogeneic stem cell transplantation (allo-HSCT) as far as possible and avoid high-risk allo-HCST (3, 4). In addition, people were advised to consult their GPs if they experienced any symptoms, particularly respiratory, during the period of confinement. Such symptoms, when linked to AML, indicate a very advanced state of the disease. These recommendations may have been translated differently depending on the local epidemic context and healthcare organization-related constraints leading to heterogeneous impact of the pandemic on the management of AML. Indeed, differences in strategies and covid-19-related outcome among AML patients were described by Wilde et al. in two hospitals, in the USA and Italy, based respectively on extensive use of outpatient care whenever possible, and an inpatient isolation protocol, with lower number of Covid-19 cases and better outcomes in the first site for the first month of the pandemic (5).

In France, the government put in place an initial lockdown that lasted from March 17 to May 10, 2020, and health authorities partnered with all hospitals, including cancer centers, to open and expand their intensive care unit beds to COVID-19 patients during the peak phase of the epidemic. Non-

urgent surgery requiring intensive care unit beds in the post-operative period had to be postponed in some cases (6). After the first lockdown setting up, evidences of a reduction in the number of patients managed within the national network of comprehensive care centers for newly diagnosed cancer including acute leukemia (7), as well as in the multidisciplinary team meeting activity at the regional scale (8), support the detrimental effect of the pandemic on cancer timely diagnosis and treatment initiation. According to simulation study under different scenarii of care delays absorption, acute leukemia has been expected to be associated with one of the strongest increase in cancer death for patients treated in France in 2020 due to the pandemic (+ 8 to 13%), likely consistent with diagnosis and treatment delay, and overload in hospital resources needed (9). In the present study, entitled COVAML, we aim at providing an overview of the temporal variation of AML patients characteristics and outcome in relation with the 2020 COVID-19 pandemic and its management from an interregional cohort including systematically all patients treated for a newly diagnosed AML in the south-West area (covering more than 6 million inhabitants), ensuring representativeness regarding this population.

Methods

Our study (COVAML) is based on the DATAML prospective observational cohort including all adult patients with an incident AML in the Midi-Pyrénées and Aquitaine regions since 2007. The cohort design, data collection and data processing have been approved by the national ethical authorities: The National Consultative Committee on Personal Information Processing (CCTIRS (ref 15.319) and The French National Data Protection Authority (CNIL (ref 915285)).)). Patients are included in DATAML from their diagnosis and regular updates ensure vital status documentation. Written informed consent was obtained in accordance with the Declaration of Helsinki, allowing for the collection of clinical data in the anonymized database. In the present study, we describe the evolution of several clinical indicators

reflecting AML seriousness over 2020 in comparison with 2015-2019 period, which reflects the pre-Covid-19 era. Along with patients' sex, age, socioeconomic position, and date of death, we used data on white blood cells (WBC), platelets, hemoglobin, and blasts counts (10). In absence of data on individual socioeconomic position(11), we used the French version of the European Deprivation Index, a validated and broadly used to investigate social disparities in cancer (12-14). We took patients' socioeconomic position into account as social inequalities in COVID-19 management and its impact on other health aspect have been documented in papers in France(15, 16).

In a first step, we defined 30, 60, and 90-day mortality from the date of AML diagnosis, which corresponds to the date of inclusion in DATAML. From the reference period, we computed monthly expected number of deaths and compare them with the corresponding observed numbers for the year 2020 for each month. Absolute differences in death numbers along with standardized mortality ratio (SMR) with 95% CI are provided in figure 1A (17). At the time of the study, follow-up data collection had not yet started for the year 2021, so only patients enrolled in September 2020 or earlier had 90-day survival data. Moreover, to account for fact that 30-day mortality of patients diagnosed in January or February 2020, and 60-day mortality for patients diagnosed in January 2020 have unlikely been affected by COVID-19 pandemic management which started really in March, sensitivity analyses excluding these patients were carried on.

In a second step, we describe the values distribution of the clinical indicators in terms of monthly proportions of extreme values over the whole study period. Thus, we computed the proportion of patients with hemoglobin concentration lower or equal to the first quartile (corresponding to 8.1 g/dL) of the whole distribution and we assume this as reflecting anaemia. For WBC, we computed the proportion of patients with a concentration either lower or equal to the first decile (1.21 G/L), or higher or equal to the last decile (139.5G/L) of the whole distribution. We assume these conditions to reflect respectively leukopenia or hyperleukocytosis. Subgroup analyses investigate the proportion of WBC equal or higher than the last decile among

patients with either cytological (FAB M5), or molecular profiles (NPM1 of FLT3 mutations) more prone to present hyperleukocytosis, and the proportion of WBC lower or equal than the first decile among the other patients are provided. See supplemental files for details. For platelets, we computed the proportion of patients with a concentration lower or equal to the first quartile (32G/L) of the whole distribution, assumed to reflect thrombocytopenic condition. These populational-based thresholds are fairly close to commonly used clinical severity cut-offs (e.g., hemoglobin 7.0 g/dL, platelets 20 G/L, white blood cells<1.0 G/L, white blood cells >100.0G/L). However, we choose to focus on the parameter distribution over the population as our intent was to explore temporal changes in the distribution of parameters at diagnosis, considered as marker of potential severe or at least frail clinical conditions, in relation with the 2020 COVID-19 pandemic and management. We compared the characteristics of patients from 2015-2019 with those included in 2020 and we used time series method to provide a more precise description of the indicator evolution over time. We provide the monthly rates with 95% confidence interval (CI) for both 2020 and the reference period, as well as the monthly difference with 95%CI between 2020 and the reference period (figures 2 to 5). We also represent the indicators' monthly evolution for the 2020 and the 2015-2019 periods after smoothing using moving average methods using a timescale of 8 weeks as it grossly corresponds to the length of the lockdowns. For each indicator and each time interval, we computed the absolute difference between the smoothed observation in 2020 and the average of the corresponding smoothed values for the reference period (see supplemental files). We assume that an increase in the monthly proportion of patients diagnosed for AML with extreme values of blood cells, white blood cells and platelets, would, if concomitant with COVID-19-related lockdown, may translate delayed diagnosis. Statistically significance level was considered at a threshold of 0.05. Analyses were carried on using STATA (StataCorp LP, College Station, TX, version 15.1) and RStudio (version 4.2.2 *Innocent & Trusting)*.

Results

Over the 2144 patients included in DATAML in the 2015-2020 period. The characteristics of the patients are provided in table 1 which describes both the clinical characteristics and the proportion of early deaths, i.e., at 30, 60, or 90-day post diagnosis. Patients were treated with intensive chemotherapy, hypomethylating agents or supportive care according to age, performance status and comorbidities. Patients diagnosed in 2020 received less often intensive treatment than those diagnosed in the 2015-2019 period which was confirmed by testing the associations between intensive treatment as the outcome and the period (Odds-ratio [95% Confidence Intervals] 2020 vs 2015-2019 = 0.54 [0.39; 0.74]) in multivariate model adjusted for age, performance status and comorbidities. Atwo-day delay in the median time to curative intent treatment initiation was observed in 2020 compared to 2015-2019 patients, but not statistically significant at the threshold of 0.05. .As expected, we found no statistically significant differences in sex-ratio, in the proportion of early deceases nor in the patients' characteristics between 2020 and the 2015-2019 period. Sensitivity analyses for provided very similar results: 13% (2020) vs 12.7 (2015-2019) for 30-day mortality, and 21.6% (2020) vs 22.5 (2015-2019) for 60-day mortality with no statistically significant associations. No differences were found regarding patients' socioeconomic position assessed by EDI. In the rest of the analyses, results are provided for complete cases for each indicator, representing at worse 10.2% of missing data (for blasts).

Table 1. Patients characteristics according to the inclusion period, either 2015-2019 or 2020. (Total N = 2 144).

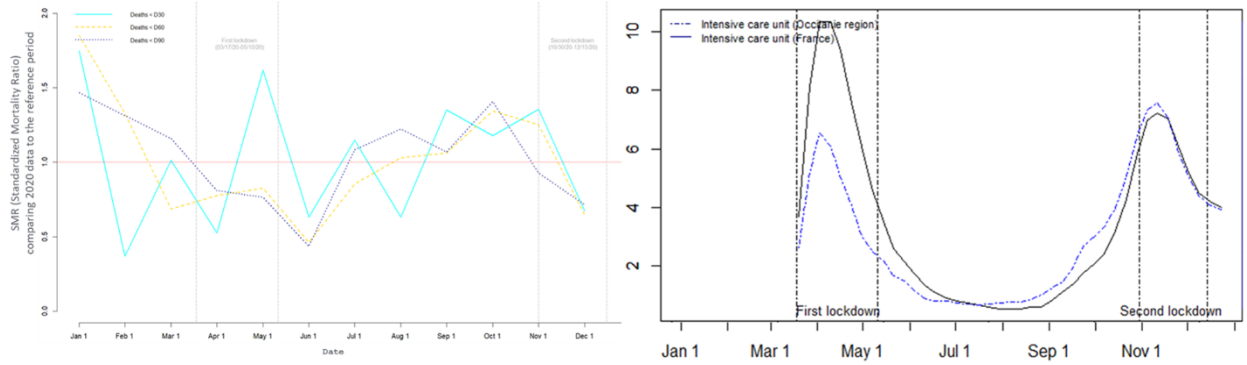
		2015-2019 (N_1 = 1 714)		2020 (N_2 = 430)		p-value
		N (%)		N (%)		
Sex	Men	935	(55)	251	(58)	0.166[2]
	Women	779	(45)	179	(42)	
Age at diagnosis (median (IQR[1]))		69	(59-78)	71	(61;79)	0.065[3]
Deceased within the first 30 days post diagnosis	yes	215	(13)	53	(12)	0.899[2]
	no	1 499	(87)	377	(88)	
Deceased within the first 60 days post diagnosis 2	yes	383	(22)	92	(21)	0.667[2]
	no	1 331	(78)	338	(79)	
Deceased within the first 90 days post diagnosis	yes	492	(29)	121	(28)	0.811[2]
	no	1 222	(71)	309	(72)	

Hemoglobin in g/dL (median (IQR[1]))		9.1	(8.1-10.6)	9.0	(7.9-10.5)	0.186[3]
Number of missing values)		40		15		
White blood cells in G/L (median (IQR[1]))		6.0	(2.1-29.2)	5.8	(2.0-24.7)	0.358[3]
Number of missing values		45		15		
Platelets in G/L (median (IQR[1]))		61	(31-109)	65	(34.0-118.0)	0.163[3]
Number of missing values		49		23		
Blasts in % (median (IQR[1]))		19	(4.1-53.0)	22	(6-55)	0.100[3]
Number of missing values		145		74		
Intensive chemotherapy	Yes	922	(54)	191	(45)	<0.001[2]
	No	788	(46)	238	(55)	
Number of missing values		4		1		
Time to curative-intent treatment initiation (median(IQR)		6	(2-18)	8	(3-18)	0.062[3]
Number of missing values (supportive care)		86		23		
Living in an area associated with EDI scores (in quintile from the national distribution of EDI scores)	Quintile 1 – less deprived	295	(18.3)	60	(15.1)	0.373[2]
	Quintile 2	299	(18.5)	86	(21.6)	
	Quintile 3	321	(19.9)	81	(20.4)	
	Quintile 4	391	(24.2)	102	(25.6)	
	Quintile 5 – most deprived	308	(19.1)	69	(17.3)	
	Missing values	100		32		

[1] Interquartile range = Q1-Q3, [2] Pearson Chi2 test, [3] Wilcoxon rank sum test.

The temporal evolution of standardized mortality ratios (SMR) comparing deaths occurring at 30 days, 60 days, and 90 days post diagnosis in 2020 with the reference period (2015-2020) are summarized in figure 1A. The curves did not show any clear under or over-early-mortality among AML cases included in the study during the lockdown. Detailed SMR values with confidence intervals, as well as the observed and expected numbers of deaths per month, are provided in supplemental files (table S1), supporting none SMR statistically significantly different from 1.

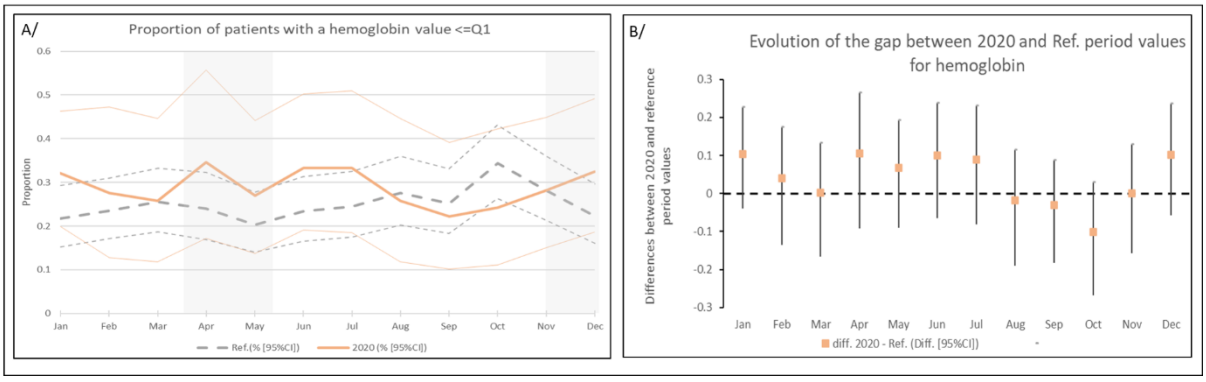
Figure 1. Evolution of the SMR (2020 vs 2015-2019 (ref.) of death in 30-, 60-, 90-days post inclusion (left-side (A)) and ICU beds occupation rates over the pandemic course in 2020 (right-side (B))



Figures 2 to 5, for the A part, represent the monthly proportion of patients with extreme values for different clinical markers in 2020 compared to 2015-2019. The differences in these monthly proportions for 2020 and 2015-2019 are presented in the B part. In figure 1B, we provide the occupation rates of ICU beds in France and in the region as a witness of the general and local epidemic contexts evolution. In supplemental files (figures S3 to S6), we provide the smoothed distribution of the differences of patients' clinical characteristics in 2020 compared to 2015-2019 in red and the national and local context in background.

Figure 2 presents results for hemoglobin. In figure 2.A, before August there were higher proportions of patients diagnosed with low hemoglobin values in 2020 than in the prior five years, with a maximum within the first lockdown. The same phenomenon was observed in December. However, these differences were not statistically significant (Figure 2.B).

Figure 2. Evolution of the difference in proportion (per month) of subjects with a hemoglobin value less than or equal to the first quartile Q1, between 2020 and the reference period (2015-2019). COVAML study, metropolitan France, 2015-2020 (n = 2 089)



Results for white blood cells are given in figure 3 showing no clear pattern. Among patients with either cytological (FAB M5) or molecular factors (NPM1 of FLT3 mutations) associated with the risk of hyperleukocytosis, subgroup (n=579, 123 patients from 2020 and 456 for 2015-2019) analyses results show no clear pattern in the difference in proportions of patients with high WBC values in 2020 and 2015-2019 data (Supplemental files, figures S1). Among the other subgroup, not at higher risk of hyperleukocytosis, the distribution gap between the proportion of low WBC values in 2020 compared to 2015-2019 increased after the first lockdown. None of these patterns were nevertheless statistically significant.

Figure 3. Evolution of the difference in proportion (per month) of subjects with a white blood cell value less than or equal to the first decile D1 or greater than or equal to the ninth decile D9, between 2020 and the reference period (2015-2019). COVAML study, metropolitan France, 2015-2020 (n = 2 084).

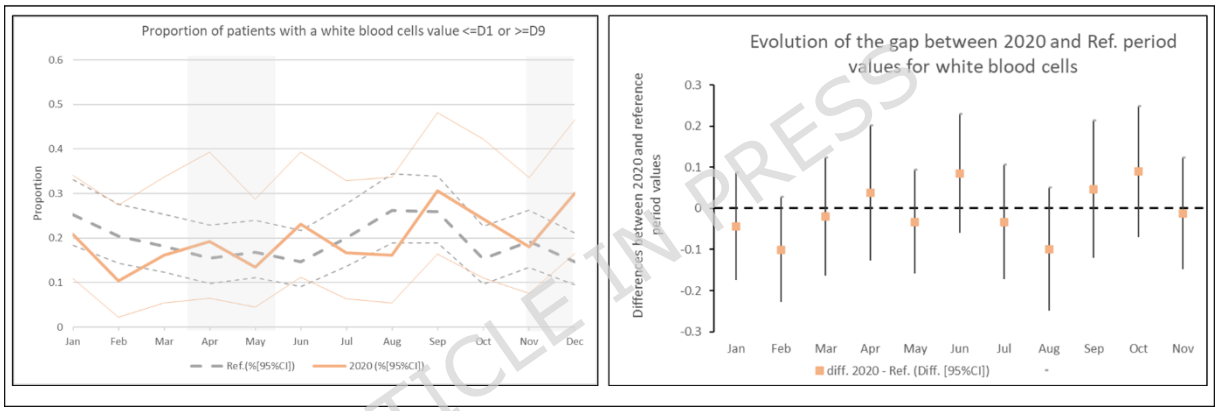
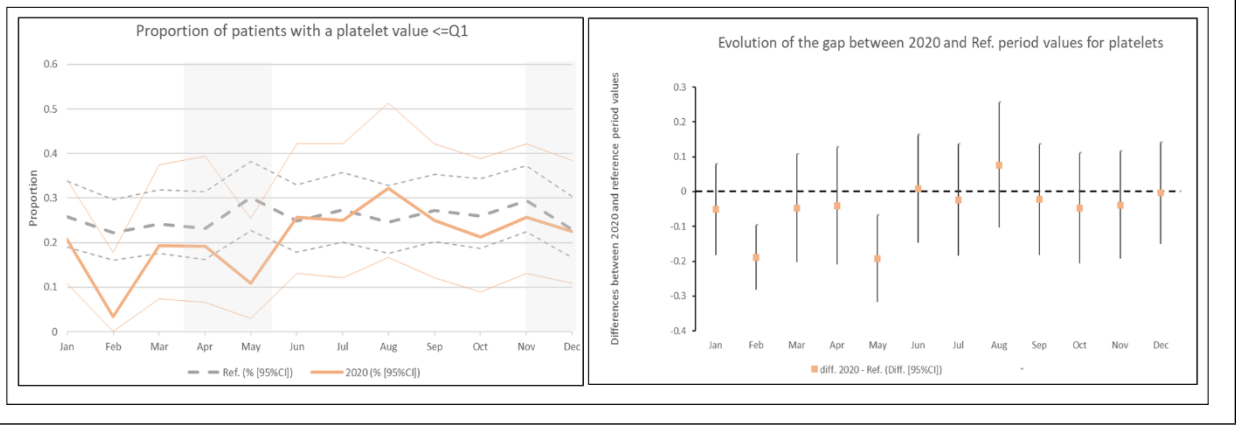


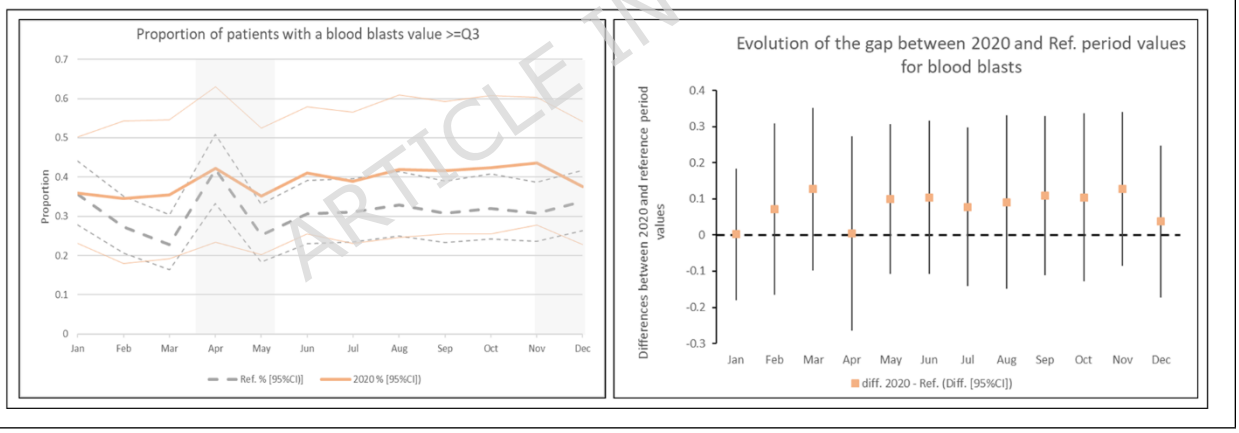
Figure 4 presents results for platelets concentration. The monthly proportion of patients with low values of platelets values for 2020 were statistically significantly lower than in 2015-2019 around the first lockdown. A positive but non-significant difference was observed in August.

Figure 4. Evolution of the difference in proportion (per month) of subjects with a platelet value less than or equal to the first quartile Q1, between 2020 and the reference period (2015-2019). COVAML study, metropolitan France, 2015-2020 (n = 2 072).



The dynamic of the distribution gap between2015-2019 and 2020 for values for blood blasts, described in figure 5, shows grossly similar but higher values for 2020 than in 2025-2019 but with no clear variations around the lockdowns.

Figure 5. Evolution of the difference in proportion (per month) of subjects with a blood blast value greater than or equal to the third quartile Q3, between 2020 and the reference period (2015-2019). COVAML study, metropolitan France, 2015-2020 (n = 1 925).



Discussion

From the DATAML prospective cohort including all adult patients diagnosed for an incident AML in South-West France, we did not find any differences between the observed and expected early mortality among AML cases from 2020 in comparison with 2015-2019 during and after the first lockdown. Bivariate comparisons between 2020 and 2015-2019 cohorts did not highlight differences in patients' characteristics. However, our results

describing the dynamics of the variations between 2020 and 2015-2019 periods suggest a slight impact of the first lockdown on the concentrations of hemoglobin and platelets, with statistical significance reached only for platelets distribution gap between the reference and covid-19 eras. Less marked patterns were found for WBC and blood blasts.

In our work, the term “COVID-19 pandemic” primarily refers to societal and healthcare system-level effects rather than to infection-related biological effects. Some of our results are similar with Martín-Moro et al. who described AML patients’ clinical characteristics, in a single-center study in Madrid, Spain. They provide evidence of worse performance status, higher proportion of bleeding, lower hemoglobin level but higher leukocytes counts without hyperleukocytosis, among AML patients diagnosed during the first lockdown period than controls from 2019 in a single center in Madrid (10). More contrasted results are provided in an Australian multicentric study in 8 metropolitan hospitals in Victoria showing no differences in AML clinical characteristics between patients diagnosed before and after the first lockdown but a three-fold augmentation in the proportion of hyperleukocytosis among those diagnosed during the second lockdown compared to those diagnosed in the reference period (18). To our knowledge, no other studies have documented the impact of Covid-19 and its management on AML patients’ characteristics at diagnosis, however, two have described the consequences on AML management. Results from a multicentric study in four Latin America countries (Mexico, Peru, Panama and Guatemala), describe dose-reductions in 50% of the newly diagnosed AML from 14 centers in 4 countries, during the first wave of the pandemic (19). A significant lowering in treatment intensity and a reduced access to HSCT with longer waiting time have been reported in a large electronic medical records-based study in US (20).

In our study, the higher proportion of patients with low hemoglobin concentration and with extreme concentration of WBC translates a higher proportion of patients with severe conditions at patient’s inclusion in DATAML, which might reflect delayed diagnoses during and after the first

lockdown. This delay might likely be due to delay in addressing patients to the university hospitals where diagnoses were confirmed and treatment discussed in multidisciplinary team meeting (MTM). Such delays are compatible with the regional observations, for all cancers combined, that documented stable periodicity of MTM but a decrease in the number of cases discussed per MTM session in all hospitals in the region (8), notably for the cases discussed for the first time. However, we did not observe over-mortality contrarily to what would have been expected based on Bardet et al. predictions (9). Thus, we assume that this phenomenon might translate the capability of the regional healthcare system to buffer an overrepresentation of patients with more severe condition at diagnosis during and after the first lockdown period, likely reinforced by a favorable regional pandemic context. In this period, indeed none of the three centers providing intensive care for AML patients has reduced its capacity, without closing any ICU beds dedicated to hematology nor oncohematological beds. Moreover, it is very likely that this has been helped by the quite favorable regional epidemic situation, illustrated by the large gap between the national and the regional ICU-attendance rates during these periods illustrated in figure 1B. However, a lesson to be drawn from our results is that, despite a favorable context, the Covid-19 pandemic and the first lockdown still might have skewed the 2020 distribution of AML cases with severe conditions away from pre-Covid-19 expectations, even modestly. It is also noteworthy that, our results showed a statistically significant lower proportion of intensive treatment in 2020 in comparison with 2015-2019 and a two-day delay in the median time from diagnosis to curative intent treatment initiation (not statistically significant ($p=0.062$)) despite the fairly favorable pandemic context in the region. This gives an idea of what would have happened in less favorable contexts, such as in north-eastern France or the Paris region, where Covid-19 incidence was higher and intensive care units were overwhelmed (21).

The main limitation of our study was to be restricted to a sub-national level, in South-West France which still represented more than 6.4 million of inhabitants in 2020. Thus, our results must be put into perspective with local

and national epidemic contexts. As a patients-based registry, DATAML systematically recruits all AML diagnosed in one of the hospitals of the regions included in the study. Untreated cases are very rare, limiting the selection bias in DATAML population, because AML is an hematological emergency engaging the vital prognosis that requires treatment as soon as possible. Therefore, we can reasonably assume our result to provide an unbiased picture of how AML patients' management and outcome have been impacted by both the Covid-19 outbreak and the first lock setting-up in the region. In addition, no data on SARS-CoV-2 infection among patients were available but this does not impact our work because we were mainly interested in he consequences of the pandemic strain on the healthcare system.

Conclusion

There are no data at the national level for documenting the impact of both Covid-19 outbreak and the first lockdown setting-up, especially including regions wherein healthcare system was under high-strain. Our observations took place in a fairly favorable context where health care system was not overwhelmed, but we still pointed out that the 2020 distribution of AML cases with severe conditions has been deviated from pre-Covid-19 expectations, even modestly. Thus, it is very likely that the pattern we described here have been actually worse in the regions with higher incidence rates and ICU occupancy levels.

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Authorship

SL, AP, CR, PYD and SB designed the study. AS and ACDG collected data. AS, ACDG, and EB controlled data quality. SL and RF designed the statistical analyses and analyzed the data. All authors have reviewed and discussed

the results. SL RF PYD CR SB wrote the paper and all authors reviewed and corrected the paper.

Data availability statement

The DATAML database is coordinated by CR and SB for the eastern sub-cohort and by PYD and AP for the western part. The data are accessible on demand formulated to the coordinators and will be assed according to the DATMAL data sharing agreement. All research teams, whether French or foreign, wishing to use DATAML cohort data must submit a request to Prof. Christian Récher (recher.christian@iuct-oncopole.fr) or Dr. Sarah Bertoli (bertoli.sarah@iuct-oncopole.fr) for the LAM Toulouse cohort and/or Prof. Arnaud Pigneux (arnaud.pigneux@chu-bordeaux.fr) and Dr Pierre-Yves Dumas (pierre-yves.dumas@u-bordeaux.fr) for the LAM Bordeaux cohort) in the form of a synopsis that is sufficiently detailed to assess the scientific and methodological quality of the project. The project methodology must be validated by Dr Emilie Bérard (emilie.berard@utoulouse.fr). This may involve using available data and/or collecting additional data for a specific purpose. In the event of additional data collection, the applicant must obtain regulatory approvals relating to data confidentiality (authorization from the CNIL) and/or an ethics committee.

Ethics approval

The cohort has been approved by the national ethical authorities (CCTIRS (ref 15.319) and CNIL (ref 915285))

Patients consent

All patients included in the DATAML cohort received and signed the information notice to express their non-opposition for the use of their data for research.

Conflicts of interest statement

PYD declares a consulting or advisory role with Daiichi-Sankyo, Jazz Pharmaceutical, Astellas, Abbvie, Celgene, Janssen, BMS, Gilead, Novartis,

and Servier. CR declares a consulting or advisory role with Abbvie, Amgen, Astellas, BMS, Boehringer, Jazz Pharmaceuticals and Servier, and received research funding from Abbvie, Amgen, Astellas, BMS, Iqvia and Jazz Pharmaceuticals. SB declares a consulting or advisory role with Abbvie, Astellas, BMS-Celgene, Jazz Pharmaceuticals and Servier

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Figures legends:

Figure 1

Legend :The curves in cyan, orange, and dark blue correspond to deaths with 30-day, 60-day, and 90-day post inclusion periods, respectively.

Figure 2

No legend

Figure 3

No legend

Figure 4

No legend

Figure 5

No legend