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Impact of pre-transplantation sinus abnormalities assessed by Lund-Mackay scoring system on sinusitis occurrence after allogeneic hematopoietic cell transplantation in acute leukemia patients

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Abstract: Introduction: Screening sinonasal evaluation is routinely performed before allogeneic hematopoietic cell transplantation (allo-HCT), however, data supporting such evaluation is inconsistent. Objectives: Assessment of the utility of screening sinonasal evaluation with computed tomography (CT). Methods: A retrospective analysis of acute leukemia patients who underwent allo-HCT, for whom screening sinonasal CT scans were reevaluated, and for whom Lund-Mackay score (LMS) was calculated. Results: Forty-eight patients, the median age at allo-HCT 38 years (18–58), 52% males, were included. 79% had acute myeloid leukemia (AML), 21% acute lymphoblastic leukemia (ALL). Conditioning intensity was myeloablative in 96% of patients, 21% of patients received total body irradiation. 19% of patients had a history of sinusitis before allo-HCT.

Screening sinus CT was performed a median of 22 days before allo-HCT. The median LMS was 1 point (0–10). The severity of sinus abnormalities was: no abnormalities (31%), mild (67%), moderate (2%), severe (0%). Mucosal thickening was the most frequent abnormality (69%).

Eleven patients experienced sinusitis after a median of 93 days (11–607) after allo-HCT. 1-year cumulative incidence of sinusitis was 22%. No threshold of LMS and no type of sinus abnormalities were correlated with sinusitis development after allo-HCT.

Mild sinus disease at screening did not negatively impact survival in comparison to no sinus disease.

Conclusions: Despite the fact, that majority of analyzed patients had either no or mild sinus disease at screening a significant proportion of patients developed sinusitis after allo-HCT. Evaluation of LMS before allo-HCT did not help predict the development of sinusitis after the procedure.

Key words: allogeneic hematopoietic cell transplantation, allo-HCT, sinusitis, Lund-Mackay scoring system, computed tomography, screening.

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Introduction

Allogeneic hematopoietic cell transplantation (allo-HCT) constitutes the standard of care for the majority of transplant-eligible acute myeloid leukemia (AML) and acute lymphoblastic leukemia (ALL) patients. While it has the potential to be curative in a proportion of these patients [1, 2], allo-HCT may simultaneously be associated with serious complications, among which graft versus host disease and infectious complications pose the greatest risk to the patient [3]. Therefore, different screening techniques are undertaken before transplantation to identify the risk of these complications in the post-transplantation period. Among them, screening sinonasal evaluation belongs to the ones routinely performed.

Despite the fact, that sinusitis is a common medical problem in the general population, data on this condition in patients undergoing allo-HCT are limited [4]. Research analyzing this issue concerned both allo-HCT (mostly in patients with chronic myelogenous leukemia, CML) and autologous hematopoietic cell transplantation [5–11]. Since the rate of allo-HCT for CML has dramatically declined [12], a significant proportion of the literature data on post-transplantation sinusitis do not apply to AML and ALL patients. Additionally, also the data on the impact of sinonasal evaluation performed before allo-HCT is inconsistent. Some authors were not able to find any relationship between the results of the pre-HCT sinonasal evaluation and post-HCT outcome [13–15]. On contrary, the others found, that the severity of radiographic sinus disease on pre-HCT CT scans correlated with clinical and radiographic sinusitis later in the post-HCT course, and was associated with a trend toward decreased survival [16]. Importantly, both Zamora *et al.* [14] and Billings *et al.* [16] analyzed pediatric but not adult population, and additionally, Billings *et al.* analyzed both auto- and allo-HCT patients [16]. Because of these inconsistencies and lack of up-to-date data consistent with current clinical practice, we decided to elucidate the correlation of results of the pre-HCT sinonasal evaluation performed with computed tomography (CT) with post-allo-HCT sinusitis development and overall patients' outcome in the group of adult acute leukemia patients.

Materials and Methods

This study was approved by the Ethical Board of the Medical University of Warsaw (Approval ID: AKBE/114/15) and was performed in accordance with the Declaration of Helsinki. The patients gave informed consent for treatment and the follow-up analysis. No additional consent was obtained for this retrospective analysis of the data.

Patients

For the study, we selected patients diagnosed with acute leukemia, either myeloid or lymphoblastic, who underwent allo-HCT between October 1999 and June 2010, who had a screening sinus CT scan performed within 56 days before transplantation. The screening sinus examination was reevaluated retrospectively for the purpose of this study to assess the magnitude and the character of the abnormalities.

Data on age at transplantation, sex, underlying hematological disease, disease status at diagnosis, intensity of conditioning (myeloablative vs reduced intensity), total body irradiation (TBI) use, source of stem cells, donor type, history of previous sinusitis were obtained from the medical records of the patients.

Evaluation of CT scans

Computed tomography scans, both at screening and at sinusitis diagnosis (if performed), were evaluated for calculation of Lund-Mackay score (LMS) [17, 18]. Accordingly, the left and right ethmoid, maxillary, frontal, and sphenoid sinuses were given a score from 0 to 2 each, where 0 denoted a clear sinus, 1 — partial opacity, and 2 — total or near-total opacity, secondary either to mucosal thickening or fluid levels. The osteomeatal complexes were also assigned a score from 0 or 2, denoting their patency or occlusion. The severity of sinus disease was graded as in the study of Fulmer *et al.* [9] i.e., no disease (score: 0 points), mild disease (score: 1–6 points), moderate disease (score: 7–12 points), and severe disease (score: 13–24 points).

Statistical analysis

Continuous variables were summarized using median (range), while frequency tables were used for categorical variables.

To identify the radiological abnormality in the pre-allo-HCT CT scan (i.e., LMS with specific cut-off value, combined CT findings, total sinus opacification, frothy secretions, fluid levels, mucosal thickening) with the highest predictive value for sinusitis occurrence in the post-allo-HCT period, receiver operator characteristic (ROC) analyses were carried out. Comparison of relative statistical power was performed with area under the curve (AUC).

Sinusitis incidence was assessed by means of competing risks analysis. For sinusitis we considered death without sinusitis as a competing event and vice versa. Sinusitis incidence was evaluated at 30 days, 100 days, and 1 year along with 95% confidence intervals (95% CI).

Overall survival (OS) was estimated by the Kaplan-Meier method. Survival was calculated from the day of allo-HCT. Follow-up was censored at the date of the last

contact among survivors. Overall survival was compared among patients depending on the severity of sinus disease. For patients in whom sinusitis was diagnosed after the second transplantation, survival and time to sinusitis were calculated from the date of the first transplantation. For the timing of sinusitis also the time from the second allo-HCT was provided. OS is reported both as a median and 2-year estimate along with the 95% confidence interval (CI).

Results

Study population and patients' characteristics

Altogether 48 patients fulfilling the selection criteria, i.e. having a CT performed during screening, were identified. There were 25 males (52%); the median age was 38 years (range 18–58). Thirty-eight (79%) patients were diagnosed with AML, while 10 (21%) with ALL. Patients' demographics and transplants' characteristics are shown in Table 1.

Table 1. Patients' and transplants' characteristics. Data are shown for the whole group and for acute myeloid leukemia (AML) and acute lymphoblastic leukemia (ALL) patients separately (BM — bone marrow, CB — cord blood, CR — complete response, MAC — myeloablative conditioning, PB — peripheral blood, RIC — reduced intensity conditioning, TBI — total body irradiation).

	Whole group	**AML**	**ALL**
Number of patients	48	38	10
Age at allo-HCT	38 (18–58)	41 (18–58)	24 (19–51)
Sex			
Male	25 (52%)	18 (47%)	7 (70%)
Female	23 (48%)	20 (53%)	3 (30%)
Disease status at allo-HCT			
CR	41 (85%)	31 (82%)	10 (100%)
No CR	7 (15%)	7 (18%)	0 (0%)
Conditioning			
MAC	46 (96%)	36 (95%)	10 (100%)
RIC	2 (4%)	2 (5%)	0 (0%)
TBI	10 (21%)	0 (0%)	10 (100%)
Source of stem cells			
PB	41 (86%)	33 (87%)	8 (80%)
BM	5 (10%)	4 (11%)	1 (10%)
CB	2 (4%)	1 (2%)	1 (10%)
Donor type			
Identical sibling	29 (60%)	22 (58%)	7 (70%)
Other	19 (40%)	16 (42%)	3 (30%)
History of previous sinusitis	9 (19%)	7 (15%)	2 (20%)

Screening computed tomography

Screening sinus CT was performed a median of 22 days before transplantation (range 7–45). The results of the screening are depicted in Table 2. One patient had a puncture of the maxillary sinus performed before allo-HCT; no patient required surgical treatment.

Table 2. Screening sinus computed tomography (CT). Data are shown for the whole group and acute myeloid leukemia (AML) and acute lymphoblastic leukemia (ALL) patients separately.

	Whole group	**AML**	**ALL**
Time between sinus CT and allo-HCT (day 0), days, median (range)	22 (7–45)	25 (7–44)	11 (7–45)
Lund-Mackay score; median (range)	1 (0–10)	2 (0–10)	1(0–2)
Severity of sinus disease			
No disease (0 points)	15 (31%)	13 (34%)	2 (20%)
Mild (1–6 points)	32 (67%)	24 (63%)	8 (80%)
Moderate (7–12 points)	1 (2%)	1 (3%)	0 (0%)
Severe (≥13 points)	0 (0%)	0 (0%)	0 (0%)
Type of sinus abnormalities			
Combined CT findings	4 (8%)	3 (8%)	1 (10%)
Total sinus opacification	1 (2%)	1 (3%)	0 (0%)
Frothy secretions	0 (0%)	0 (0%)	0 (0%)
Fluid levels	3 (6%)	2 (5%)	1 (10%)
Mucosal thickening	33 (69%)	25 (66%)	8 (80%)

Sinusitis after allo-HCT

Altogether, 11 patients developed sinusitis after a median of 93 days (11–607) after allo-HCT, with only 1 patient developing sinusitis after more than a year. One patient developed sinusitis shortly after the second allo-HCT (20 days; 237 days from the first allo-HCT). Four patients did not have a confirmatory CT performed, but all of them complained of symptoms mandatory for sinusitis diagnosis as specified in the European Position Paper on Rhinosinusitis and Nasal Polyps (EPOS) criteria [19] and experienced sinusitis in the late post-transplantation period (i.e., after 200, 296, 328 and 607 days). All other patients did have a CT scan performed, with a median LMS of 13 points (7–16); 14 (10–16) for AML, and 10 (7–16) for ALL. Precise data on clinical details, radiological findings, and timing of sinusitis are presented in Table 3. None of the patients who experienced sinusitis did have a history of previous sinusitis.

Table 3. Detailed characteristics of sinusitis after allo-HCT (AML — acute myeloid leukemia, ALL — acute lymphoblastic leukemia, IFI — invasive fungal infection, VRE — vancomycin-resistant *Enterobacteriacae*).

Patient	Diagnosis	L-M score at screening	Timing of sinusitis	L-M score at sinusitis	Symp-toms	Fulfilled EPOS criteria	Conomitant infections	Recur-rence of sinusitis
1	AML	0	237 (20 days after the 2nd allo-HCT)	10	No (solely fever)	No	IFI	No
2	AML	2	15	16	Yes	Yes	VRE sepsis	No
3	AML	0	14	14	No (solely fever)	No	No	No
4	AML	3	328	Not done	Yes	No	No	No
5	AML	3	200	Not done	Yes	No	No	Yes
6	AML	2	607	Not done	Yes	No	No	No
7	AML	1	296	Not done	Yes	No	Laryngitis	Yes
8*	ALL	1	93	7	No	No	Pneumonia	No
9	ALL	1	20	13	Yes	Yes	IFI	No
10	ALL	0	11	16	Yes	Yes	S. epidermidis methycyllin-resistant sepsis	Yes
11	ALL	1	21	7	No (solely fever)	No	No	No

* Confirmed fungal sinusitis (Aspergillus spp.)

Thirty-day cumulative incidence of sinusitis assessed using competing risks analysis reached 6% (95% CI, 2–16) for the entire group, 5% (95% CI, 1–16) for AML, and 10% (95% CI, 0–37) for ALL. One-hundred-day cumulative incidence was 10% (95% CI, 4–21) for the entire group, 5% (95% CI, 1–18) for AML and 30% (95% CI, 6–59) for ALL, while 1-year incidence of sinusitis was 22% (95% CI, 11–34) for the whole group, 17% (95% CI, 7–31) for AML and 40% (95% CI, 11–68) for ALL. The difference in sinusitis cumulative incidence between patients with AML and ALL was not statistically significant, $p = 0.11$.

Impact of pre-allo-HCT sinus abnormalities on post-transplantation sinusitis development

The ROC analysis of the different magnitude of sinus disease assessed before allo-HCT with the means of Lund-Mackay score on sinusitis development after allo-HCT was performed for the whole group, and separately for AML and ALL. No cut-off value for Lund-Mackay score among the ones tested was found to be predictive for post-transplantation sinusitis (AUC = 0.491) (Fig. 1). Similarly, no specific CT findings before allo-HCT were associated with the occurrence of sinusitis after transplantation, with AUC being 0.505 for combined CT findings, 0.526 for mucosal thickening, 0.486 for total sinus opacification, 0.518 for fluid level.

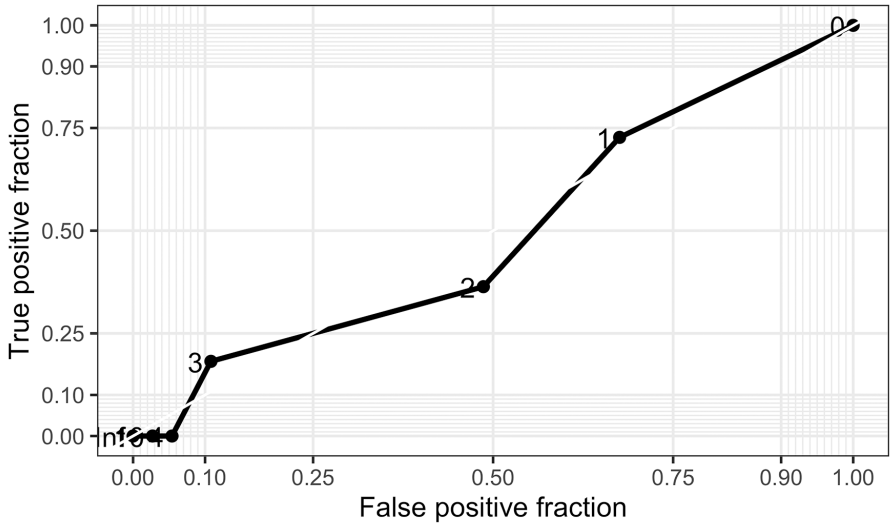

Fig. 1. ROC curve for predictive value of specific Lund-Mackay score on sinusitis development after allo-HCT.

Survival analysis

The median overall survival in the analyzed group reached 1.8 years (95% CI, 1.2-NA) for the entire group; 1.7 (95% CI, 0.8-NA) for AML and was not reached for ALL. Two-year OS for the entire group was 48% (95% CI, 34–69%): 44% (95% CI, 29–67%) for AML and 71% (95% CI, 43–100%) for ALL.

The respective survival data for patients stratified according to the severity of sinus abnormalities at screening (no disease, mild disease) are shown in Table 4. Patients with no disease had a 2-year OS of 30% (95% CI, 13–73%) compared to 57% (95% CI, 39–84%) in patients with mild disease, but the difference was not significant (Fig. 2).

Table 4. Overall survival (OS) of patients stratified according to the severity of sinus abnormalities in CT scans obtained before allo-HCT. The data is reported as the median (presented in years) and 2-year OS along with 95% confidence intervals (AML — acute myeloid leukemia, ALL — acute lymphoblastic leukemia).

	Entire group		**AML**		**ALL**	
	Median	2-year	Median	2-year	Median	2-year
No disease	0.7 (0.5-NA)	30% (13–73)	0.7 (0.2-NA)	23% (8–71)	Not reached	100% (100–100)
Mild disease	2.6 (1.7-NA)	57% (39–84)	2.6 (1.7-NA)	56% (36–87)	Not reached (1.4-NA)	66% (35–100)
p	*0.054*		*0.034*		*0.54*	

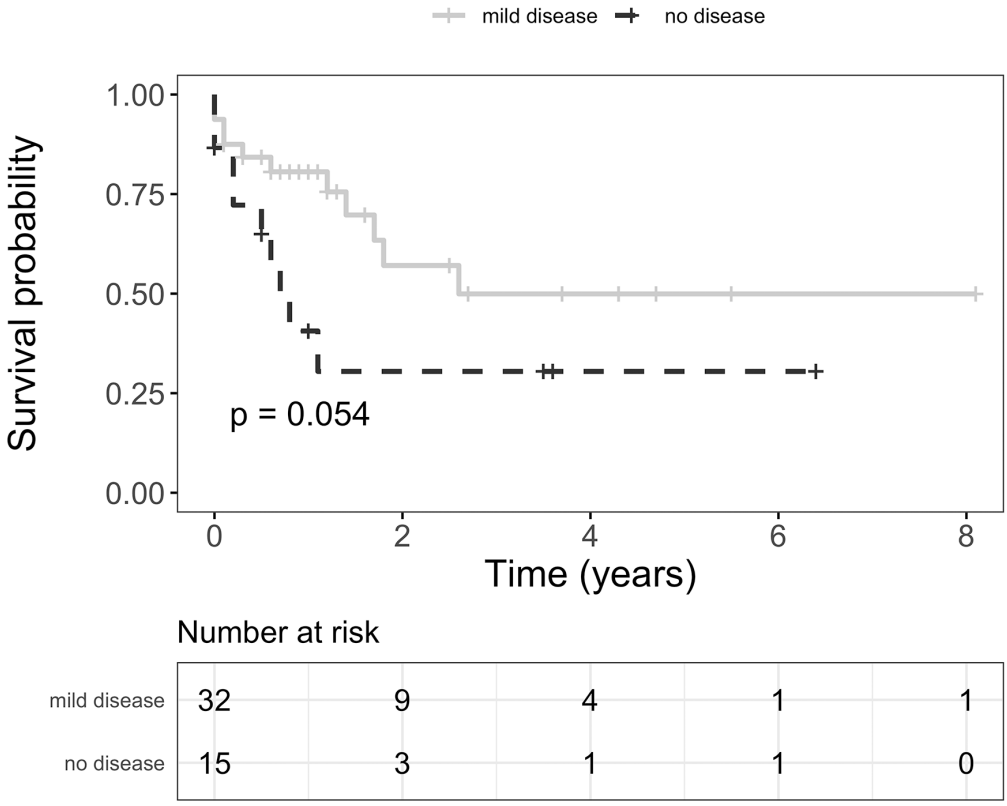

Fig. 2. Overall survival of patients stratified according to the severity of sinus abnormalities at screening (no disease, mild disease).

The only patient with moderate sinus disease at screening succumbed to Pseudomonas aeruginosa sepsis after 0.6 months without experiencing clinical sinusitis after allo-HCT.

Discussion

Screening sinus CT revealed, that the majority of patients had either no or just mild sinus disease as assessed by Lund-Mackay score. Solely one patient (2%) had the moderate disease at screening. These findings are different from the findings reported by other authors, where up to 26% of patients [14, 16] had either moderate or severe sinus disease. Mucosal thickening alone was the most frequent abnormality in the analyzed group, which also differs from the reports of others, where fluid level, frothy secretion, total or near-total opacification of the sinuses were much more prevalent [14].

Sinusitis developed in 11 patients (22.9%), which translated into a 1-year cumulative incidence of sinusitis of 22%; 17% for AML and 40% for ALL patients. The overall frequency of sinusitis was within the range of sinusitis reported by others [7, 8, 10, 20–22]. It is, however, worth mentioning, that the frequency of sinusitis in the published reports was calculated as the simple frequency of patients experiencing sinusitis, e.g. [8, 16], and not as a competing risk of death. In our opinion, the competing risk analysis seems more suitable to establish the probability of developing sinusitis, taking into consideration the fact, that a substantial proportion of patients succumbed during the observation time without developing sinusitis, and did not have a chance to develop sinusitis anymore.

Despite the fact, that patients with ALL experienced sinusitis more frequently than patients with AML, this difference did not reach statistical significance. In our opinion, it seems reasonable to treat these results with caution, as our group of ALL patients was small, and TBI which was most frequently applied for conditioning of ALL patients was reported by others as a risk factor for post-HCT sinusitis [5].

All patients in whom sinusitis developed in the post-transplantation period had a screening LMS of 0–3. For patients, for whom CT scans were performed after allo-HCT there was an increase of a total LMS to 7–16 points, an absolute increase of a median of 12 points (range 6–16). Therefore, it can be concluded, that no or mild disease as assessed by CT scans does not protect patients from developing sinusitis after transplantation, and these patients need to be carefully monitored to make a diagnosis when needed. ROC analysis did confirm, that among patients with no/mild disease it was not possible to establish the threshold of LMS, for which the likelihood of sinusitis would be increased. We were also not able to show, that specific sinus radiologic abnormalities, i.e., mucosal thickening, total sinus opacification, fluid levels, or combined CT findings did predict sinusitis development after allo-HCT. It must be emphasized, that based upon our data, we can only speculate on the impor-

tance of LMS and specific radiological findings in respect to no or mild sinus disease. There was only one patient with more advanced sinus disease, therefore, research is needed to analyze the impact of such abnormalities on the post-allo-HCT sinusitis in patients with moderate/severe screening sinus disease.

The presence of mild sinus abnormalities before allo-HCT did not influence the survival of the affected population after allo-HCT. The data on the impact of sinus abnormalities on survival are scarce, with Billings *et al.* suggesting that patients with severe sinus disease before HCT had poorer survival than those less affected [16]. It is also not clear whether sinusitis itself poses a safety risk after allo-HCT. In our previous analysis, we did show that early (within the first 30 days) sinusitis did negatively influence the survival of AML patients [20]. Therefore, until sound evidence is available, it seems advisable to monitor these patients carefully, and once the indications for treatment are found — to start appropriate therapy.

Importantly, at the time of sinusitis diagnosis, a significant proportion of patients suffered from other serious concomitant infections — 2 patients from invasive fungal infection, 2 from sepsis with antibiotic-resistant strains, 1 from pneumonia. Additionally, 1 patient suffered from laryngitis. It is worth mentioning that patients with concomitant infections did develop sinusitis both in the early but also later post-allo-HCT period, which again stresses the fact, that sinusitis awareness should be maintained throughout the entire period of observation, and especially before the immune reconstitution.

There are some important limitations to this study. First, the analysis is retrospective, which precludes the possibility of obtaining more details on the clinical presentation at sinusitis diagnosis, and also a possibility of performing any additional diagnostic tests. Second, only a limited number of patients could be enrolled. Third, there were no patients with severe, and solely a single patient with moderate screening sinus disease, which does not allow to make any conclusions concerning this group of patients.

In conclusion, sinusitis is a common complication after allogeneic hematopoietic cell transplantation. LMS assessed before transplantation in patients with no or mild disease does not help predict the development of sinusitis after the procedure. Also patients having no or mild disease at screening are at significant risk of developing sinusitis after allo-HCT.

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Disclosures

Conflict of interest — none declared.

Authors' individual contributions

J.S.: Conceptualization, Methodology, Investigation, Data curation, Software, Writing-Original draft preparation; J.D.-S.: Conceptualization, Methodology, Investigation, Data curation, Software, Writing-Original draft preparation; K.K.: Conceptualization, Statistical analysis, Writing-Reviewing, and Editing; P.B.: Conceptualization, Statistical analysis, Writing-Reviewing, and Editing; E.K.-P.: Conceptualization, Writing-Reviewing, and Editing; A.T.: Conceptualization, Writing-Reviewing, and Editing; T.G.: Conceptualization, Writing-Reviewing, and Editing; K.N.: Conceptualization, Writing-Reviewing, and Editing; W.W.-J.: Conceptualization, Writing-Reviewing, and Editing; G.W.B.: Conceptualization, Writing-Reviewing, and Editing.

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