Safety and efficacy of the BNT162b mRNA COVID-19 vaccine in patients with chronic lymphocytic leukemia

Ohad Benjamini,[1,2] Lior Rokach,[3] Gilad Itchaki,[4] Andrei Braester,[5] Lev Shvidel,[6] Neta Goldschmidt,[7] Shirley Shapira,[8] Najib Dally,[9] Abraham Avigdor,[1,2] Galia Rahav,[10,2] Yaniv Lustig,[11] Shirley Shapiro Ben David,[8] Riva Fineman,[12] Alona Paz,[13,14] Osnat Bairey,[4] Aaron Polliack,[7] Ilana Levy[15] and Tamar Tadmor[14,15] on behalf of the Israeli CLL study group (ICLLSG)

[1]Hematology Division, Chaim Sheba Medical Center, Tel-Hashomer, [2]Sackler Faculty of Medicine, Tel-Aviv University, Tel-Aviv; [3]Department of Software and Information Systems Engineering, Ben-Gurion University of the Negev, Beer-Sheva; [4]Institute of Hematology, Davidoff Cancer Center, Rabin Medical Center, Petah Tikva; [5]Department of Hematology, Galilee Medical Center, Nahariya; [6]Hematology Institute, Kaplan Medical Center, Rehovot; [7]Hematology, Hadassah Medical Center, Jerusalem; [8]Health Division, Maccabi Healthcare Services, Tel Aviv; [9]Division of Hematology, Ziv Medical Center, Safed; [10]The Infectious Disease Unit, Sheba Medical Center, Tel-Hashomer; [11]Central Virology Laboratory, Ministry of Health and Sheba Medical Center, Tel-Hashomer; [12]Department of Hematology and BMT, Rambam Health Care Campus, Haifa; [13]Infectious Disease Unit, Bnai Zion Medical Center, Haifa; [14]The Ruth and Bruce Rappaport Faculty of Medicine, Technion, Haifa and [15]Hematology Unit, Bnai Zion Medical Center, Haifa, Israel.

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Correspondence: *TAMAR TADMOR* - Tamar.tadmor@b-zion.org.il

Supplements:

Table S1: Side effects following BNT162b2 mRNA Covid-19 Vaccine in patients with chronic lymphocytic leukemia

SIDE EFFECTS	Immune response		**Total**	**Odds ratio (95% CI)**	**p-value**
	Present	**Absent**			
	n=160 (43%)	**n=213 (57%)**	**n=373**		
No	78 (43%)	102 (57%)	180	1 (ref)	
Grade 1	62 (45%)	76 (55%)	138	1.0668 (0.68-1.67)	0.78
Grade 2	6 (46%)	7 (54%)	13	1.1209 (0.36-3.47)	0.84
Not available	14	28	42	-----	---
Fever					
No	129 (43%)	174 (57%)	303	1 (ref)	
Grade 1	7 (50%)	7 (50%)	14	1.3488 (0.46-3.94)	0.58
Grade 2	8 (67%)	4 (33%)	12	2.6977 (0.8-9.15)	0.1
Not available	16	28	44	-----	---
Rash					
No	140 (44%)	178 (56%)	318	1 (ref)	
Grade 1	4 (67%)	2 (33%)	6	2.5429 (0.46-14.08)	0.27
Grade 2	1 (20%)	4 (80%)	5	0.3179 (0.04-2.88)	0.28
Not available	15	29	44	-----	---
Pain					
No	98 (45%)	122 (55%)	220	1 (ref)	
Grade 1	38 (42%)	53 (58%)	91	0.8926 (0.54-1.46)	0.65
Grade 2	5 (36%)	9 (64%)	14	0.6916 (0.22-2.13)	0.52
Not available	19	29	48	-----	---
Muscle Pain					
No	138 (44%)	179 (56%)	317	1 (ref)	
Grade 1	5 (56%)	4 (44%)	9	1.6214 (0.43-6.15)	0.47
Grade 2	1 (33%)	2 (67%)	3	0.6486 (0.06-7.23)	0.72
Not available	16	28	44	-----	---

Table S2: Adverse event ratio according to treatment status.

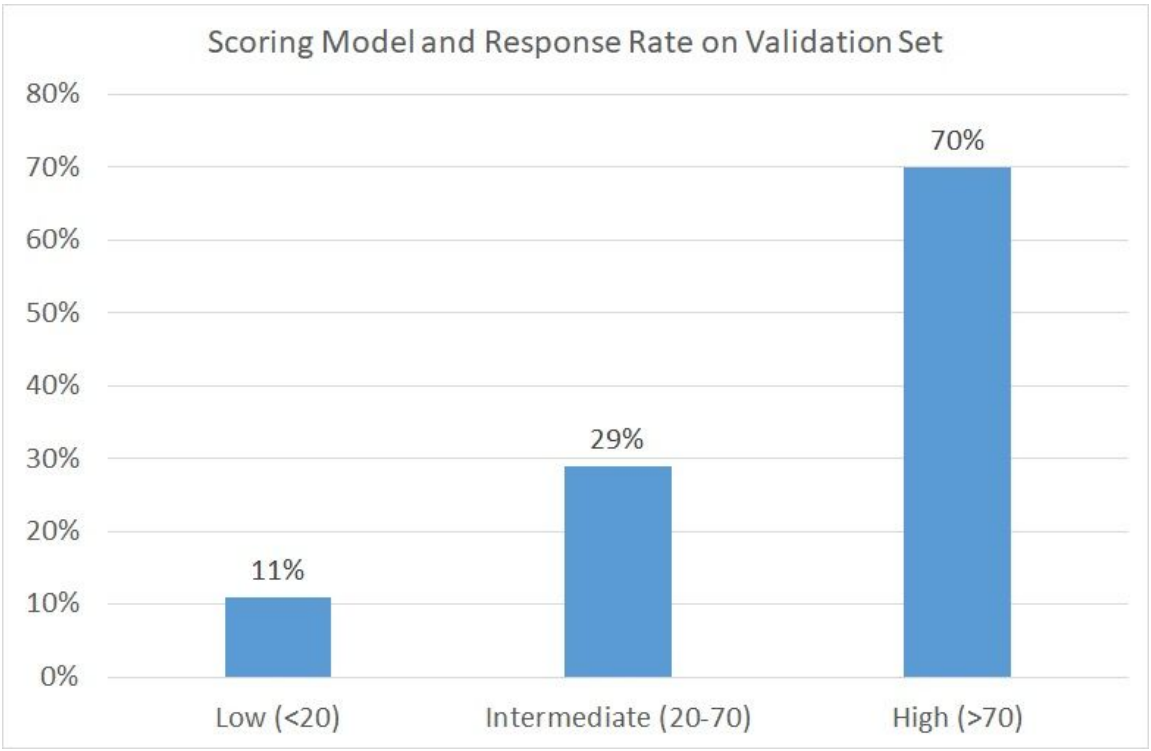
Treatment Status	**Adverse Event**		**Total**	**Odds ratio (95% CI)**	**p-value**
	Present	**Absent**			
Naïve Treatment	80 (57%)	60 (43%)	140	1 (ref)	
Currently treated	46 (43%)	60 (57%)	106	0.575 (0.35-0.96)	0.0327
Previously treated	25 (29%)	60 (71%)	85	0.313 (0.18-0.55)	0.0001

Table S3: Predictive Performance using both LASSO regression and simple risk model:

Model	**AUC**	**Classification accuracy (%)**	**Sensitivity (%)**	**Specificity (%)**
LASSO regression	0.747± 0.07	67.67%±8.78%	59.7%±6.52%	73.8±8.22%
Simple Risk Model	0.739±0.04	67.51%±5.62%	63.9%±5.95%	71%±5.5%

External Validation for Scoring Model

The proposed scoring model was performed initially by applying the cohort to the first 297 patients enrolled for model construction using 10 folds cross-validation, and subsequently on two independent external cohorts that were obtained from two new centers: 34 patients from the Galilee Medical Center and 36 patients from Kaplan Medical Center (70 patients in total). Figure S1 presents the percentage of patients that developed positive response in each risk group. As expected, the high-score group yields the highest response rate (86% vs 17% in the low score group). While model prediction performance often decreases during external validation, we observed improved discrimination capabilities both in terms of AUC (=0.821) and classification accuracy (=74%), which are slightly better than the corresponding reported values in the internal 10-folds cross-validation (AUC=0.73, Accuracy=67%). This may be due to the fact that 53% of the patients in the external cohort were therapy naïve (vs. 40.3% in the original cohort), for whom a prediction is more accurate.


Scoring Model and Response Rate on Validation Set
80%
70%
60%
50%
40%
30%
20%
10%
0%
11%
29%
70%
Low (<20)
Intermediate (20-70)
High (>70)