#4600 - Safety of BNT162b2 mRNA COVID-19 vaccine in oncologic patients undergoing numerous cancer treatment

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Introduction:

- Reported incidence of local and systemic side effects (SE) in the general population from the BNT162b2 mRNA COVID-19 vaccine is 27%
- Its **safety has not been studied** in patients with an **active cancer diagnosis** who are either ongoing or plan to undergo **oncologic therapy**

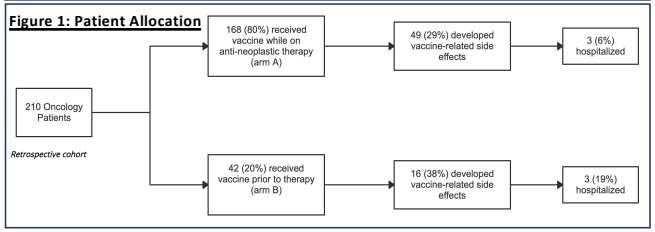
Objective:

- Assess BNT162b2 mRNA COVID-19 vaccine **safety** in **oncologic** patients on:
  - Immune checkpoint inhibitors (ICI)
  - Chemotherapy
  - Targeted therapy
  - Radiation therapy
  - Combination therapy
- Identify any relationships between **vaccine-related SE** and **specific treatment protocols** or vaccine **administration timepoint**

Methods:

- Single center (Southern Israel) retrospective cohort study:
  - Chart review of **210 patients** with an active cancer diagnosis
  - All received **2 doses** of the BNT162b2 mRNA COVID-19 vaccine
- Documentation was taken of any **vaccine related SE**, hospitalizations and/or any therapy induced adverse event (AE) exacerbations
- Patients were grouped based on vaccine administration timepoint:
  - Vaccinated ***while undergoing*** anti-neoplastic therapy (arm A)
  - Vaccinated ***prior to*** anti-neoplastic therapy initiation (arm B)

Figure 1: Patient Allocation



Results:

Table 1: Patient Demographics. Demographics of all participants and those developing vaccine related SE. * 1 pt on chemotherapy and hormonal therapy for 2 primaries. **% of pts with SE by characteristic.

	No. of Patients (%) (N = 210)	No. Patients with Vaccine Side Effects (%)** (N = 65)
Age		
Years	69 ± 11	65.2 ± 11
Sex		
Male	136 (64.8)	35 (25.7)
Female	74 (35.2)	30 (40.5)
Treatment Protocol		
Chemotherapy*	42 (20.0)	16 (38.1)
Immunotherapy	48 (22.9)	12 (25.0)
Biological	24 (11.4)	9 (37.5)
Chemo-immunotherapy	20 (9.5)	9 (45.0)
Immuno-biological	9 (4.3)	4 (44.4)
Hormonal*	43 (20.5)	7 (16.3)
Radiotherapy	3 (1.4)	2 (66.7)
Chemo-radiotherapy	2 (1.0)	1 (50)
Immuno-radiotherapy	3 (1.4)	0 (0)
Chemo-biological	16 (7.6)	5 (31.3)
Radio-Hormonal	1 (0.5)	0 (0)

Table 3: Vaccine SE Group Differences. Chi-square test showed no difference in immunotherapy vs non-immunotherapy tx or vaccine administration timepoint. Significant difference seen with gender

	All Enrolled Patients No. (%) (N = 210)	Enrolled Pts with Vaccine Side Effects No. (%)** (N = 65)
Received Vaccine		
On long term therapy (A)	168 (80)	49 (29)
1st dose / 2nd dose		30 (18) / 31 (18)
Prior to therapy (B)	42 (20)	16 (38)
1st dose / 2nd dose		11 (26) / 11 (26)
Underwent Radiation		
Within 1 mo. of vaccine	25 (11.9)	10 (40.0)
≥1 mo. after vaccine	12 (5.7)	5 (41.7)
Complications		
Therapy AE worsened	18 (8.6)	11 (61.1)
Therapy delay	10 (4.8)	9 (90.0)
Hospitalization	6 (2.9)	6 (100)
Death	4* (1.9)	4* (100)

Table 2: Side effects based on vaccination administration timepoint. No of pts that experienced SE when grouped by vaccine administration timepoint. *3 patients died from PD and 1 from unknown causes. **% of patients with side effects by group

	Number of participants	*p* - value
Immunotherapy	80	.942
Non-immunotherapy	130	
Vaccine on long term therapy (arm A)	168	.263
Vaccine prior to therapy (arm B)	42	
Males (+ SE's)	136 (35)	.027
Females (+ SE's)	74 (30)	

Results (cont.):

Table 4: Side effects following each dose of the BNT162b2 mRNA Covid-19 vaccine

Vaccine related Side Effects (N=65)	Number of patients (%)			
	Dose 1		Dose 2	
	Grade 1-2	Grade 3-4	Grade 1-2	Grade 3-4
Injection site				
Pain	30 (46.2)		18 (27.7)	
Erythema	1 (1.5)		2 (3.1)	
Edema/Induration	1 (1.5)		2 (3.1)	
Pruritis	2 (3.1)		1 (1.5)	
Headache	2 (3.1)			
Myalgia	3 (4.6)		3 (4.6)	
Arthralgia	1 (1.5)		2 (3.1)	
Chills	2 (3.1)		9 (13.8)	
Diarrhea			1 (1.5)	
Fever	1 (1.5)		7 (10.8)	
Nausea				
Fatigue	12 (18.5)	1 (1.5)	18 (27.7)	4 (6.2)
Dysarthria	1 (1.5)			
Cough			2 (3.1)	
Sore throat			2 (3.1)	
Lymphadenopathy	1 (1.5)			
Weakness	1 (1.5)		1 (1.5)	
Allergic reaction				

Conclusions:

- The incidence of vaccine-related SE in cancer patients is **consistent** with data reported for the general public (31% vs 27%).
- We believe that the BNT162b2 mRNA COVID-19 vaccine is **safe in oncologic patients** undergoing numerous cancer treatments

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