Immunotherapy Experience in Nonagenarian Veterans with Cancer

Andrew Benefield, MD, Benjamin Rush, MD, Jimmy Ruiz, MD, Mark Geraci, PharmD, Michael Goodman, MD
W. G. (Bill) Hefner VA Medical Center – Salisbury, NC

Purpose of the project: The purpose of this project was to describe the experience of treating veterans >/= 90 years of age with immune checkpoint inhibitors (ICI) for cancer.

Background:

- Immune checkpoint inhibitors (CTLA-4, PD1/PD-L1) have received broad FDA approval in most cancers, with pembrolizumab (anti-PD1 antibody) approved in any solid tumor with mismatch repair deficiency.
- As clinical use proliferates, data for their efficacy and safety in elderly populations, particularly nonagenarians, is sparse [1].
- Nonagenarians are commonly excluded from or underrepresented in clinical trials. This occurs despite the fact that the elderly embody the fastest growing portion of the population worldwide [2].
- The VA's national reach and common medical record allows us to document the efficacy and safety of these novel agents in this underrepresented demographic.

Methods: We reviewed drug exposure in Nonagenarians who received ICI within the VA system nationwide between 2016-2017 using CAPRI. We identified 48 veterans and reviewed each patient's treatment, duration of immunotherapy exposure, response, and toxicity to generate a global review on how those nonagenarians tolerated treatment. Demographic data of study participants and all endpoints have been analyzed using descriptive statistics

Results: Baseline characteristics of these 48 veterans are outlined in table 1. The primary outcome measure is duration of therapy (Table 2) with a secondary outcome being adverse events (Figure 3). Charts were also reviewed to ascertain specific cancer diagnosis, which is outlined in table 2

Table 1: Baseline Characteristics	N
Male	47
Female	1
Former Smoker	31
Active Smoker	1
Never Smoker	15
ECOG 0	2
ECOG 1	24
ECOG 2	14
ECOG 3	7
ECOG 4	0
ECOG not documented	1

Table 2: Survival	
Average Overall Survival	1.59 years**
Average Age at Initiation	91.85 years
Average # of cycles received	12.23 **
# Alive	7
# Deceased	41
** At time of data cutoff, 3/2021	

Table 3: Diagnosis

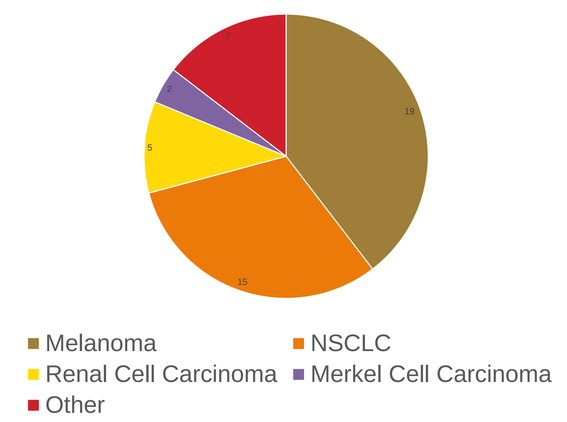

Table 4: Adverse Events		
Grade I	6 (12.5%)	(rash x2, uveitis, vitiligo, colitis, fatigue)
Grade II	4(8.3%)	(transaminitis, AKI, rash, colitis)
Grade III	2 (4.2%)	(pneumonitis, fatigue)
Grade IV	1 (2.1%)	(bullous pemphigoid)

Implications: These cases and data points illustrate that immunotherapy is being used in nonagenarians. With close monitoring of toxicities, nonagenarians with acceptable performance status can be treated with immunotherapy with their consent. Future aims will focus on the addition of more data points by expanding to include 2018.

References:
1. Lewis JH, Kilgore ML, Goldman DP, Trimble EL, Kaplan R,Montello MJ, et al. Participation of patients 65 years of age or older in cancer clinical trials. J Clin Oncol. 2003;21(7):1383–9.
2. Assunta Sgambato, Francesca Casaluce & Cesare Gridelli (2017) The role of checkpoint inhibitors immunotherapy in advanced non-small cell lung cancer in the elderly, Expert Opinion on Biological Therapy, 17:5, 565-571, DOI: 10.1080/14712598.2017.1294157