Safety of Sputnik V COVID-19 vaccine in cancer patients receiving chemotherapy: an observational study (426P)

Rumyantsev A.[1], Glazkova E.[2], Manukyan M.[1], Darenskaya A.[1], Lud H.[1], Tryakin A.[1], Tyulyandina A.[1,3]

[1]N.N. Blokhin National Medical Research Cancer of Oncology, Moscow, Russian Federation; [2]Moscow Medical City Hospital "Kommunarka"

[3]I.M. Sechenov First Moscow State Medical University

Background

Sputnik V (Gam-COVID-Vac) is a recombinant adenovirus-based vaccine against SARS-CoV-2 infection. The vaccine has shown a favorable safety profile and efficacy in Phase 3 trial and it is a main SARS-CoV-2 vaccine in Russia. There is lack of information on its safety in cancer patients. We conducted a retrospective trial to assess safety of Sputnik V in adult patients with cancer.

Methods

We screened N.N. Blokhin NMRCO records (01.2021-05.2022) and identified adult cancer patients vaccinated with Sputnik V.

The patients were asked to report any new adverse events they experienced up to 28 days after the last dose of the vaccine. All the adverse events were recorded in the database and graded according to CTCAE criteria.

Patients were specifically asked to report the following: pyrexia, asthenia, nausea, vomiting, local reactions, abdominal pain, muscle or joint pain and to report any other concerning symptoms. Symptoms were graded according to CTCAE4.03 criteria.

Results

We identified 145 patients who received at least 1 dose of vaccine, safety data were available for 141 of them. Median age was 55 years (21-83), almost half of the patients (48.9%) had gynecologic tumors. Brief pts characteristics are summarized in Table 1.

Factor	Value
Age, median	55.9 (21-83) years
Tumor primary site	
• Gynecologic tumors	70 (49.6%)
• Breast cancer	27 (19.2%)
• Genitourinary cancers	21 (14.9%)
• Gastrointestinal tumors	19 (13.5%)
• Other cancers	4 (3%)
Anticancer treatment	
• Chemotherapy	22 (15.6%)
• Endocrine therapy	18 (12.7%)
• Targeted agents*	18 (12.7%)
• Immunotherapy	4 (2.8%)
• No active treatment	79 (56.0%)

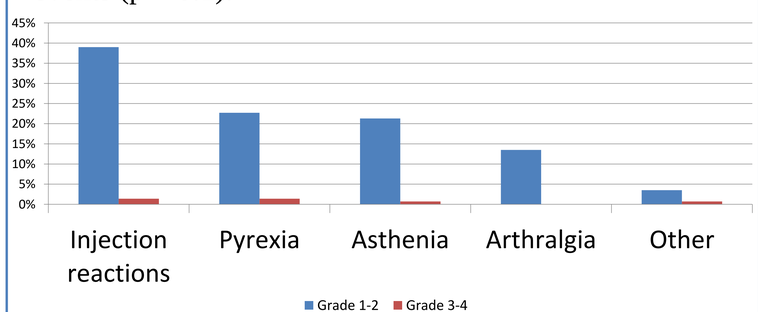
Table 1. Pts characteristics

**includes PARP inhibitors (olaparib, niraparib), CDK4/6 inhibitors (palbociclib, ribociclib, abemaciclib) and anti-VEGF/VEGFR agents*

***Note**: total % may be not equal to 100 due to rounding*

Safety

Most common AEs were injection reactions (40.4%), pyrexia (24.1%), asthenia (22.0%) and arthralgia (13.5%), results are summarized below. Six (4.2%) patients experienced grade 3-4 AEs, however one patient developed grade 4 cerebellar ataxia probably related to vaccination (described further). Cancer type and active treatment were not predictors of adverse events ($p > 0.1$).



AE of special interest

- A patient (female, 37 years) with advanced *BRCA*mut serous ovarian carcinoma, stage pT3cN0M0 received front line therapy with paclitaxel and carboplatin after upfront debulking surgery. The patient had no evidence of the disease and maintenance olaparib therapy was initiated in October, 2020.
- The patient received complete vaccination against with Sputnik V vaccine in October, 2021. Two months after the vaccination she presented to the hospital with progressive cerebellar ataxia symptoms. Diagnostic workup revealed progressive ovarian cancer without brain metastases, positive anti-Yo antibodies and cerebellar degeneration.
- The patient received second line chemotherapy with paclitaxel, carboplatin and bevacizumab with stable disease per RECIST1.1 criteria, but further neurological deterioration was observed with progressive ataxia and performance status deterioration. Cyclophosphamide therapy was initiated with stable disease and mild neurological improvement.
- Cerebellar ataxia in this patient may be a sign of paraneoplastic syndrome, however we cannot exclude its relation to the vaccine.

Conclusions

- Sputnik V vaccination appears to be safe and tolerable in patients with cancer;
- Additional studies should be conducted to assess efficacy and safety of the vaccine in cancer setting.