3. After several decades of therapeutic stagnation, clinical research in the field had led to the approval of neoadjuvant systemic therapy in key indications of urothelial carcinoma. The number of patients with muscle-invasive disease at presentation has been increasing in recent years, and the advent of effective new anti-PD-1/PD-L1 antibodies, as well as other immunotherapeutic agents, has led to a paradigm shift in the management of patients with advanced urothelial carcinoma. This has led to a change in the approach to treatment, with a focus on earlier intervention and the development of novel combination therapies.

Patients and methods

Tumor recurrence and histological subtypes (NMIBC vs. muscle-invasive bladder cancer [MIBC]) is a deadly disease, for which several different agents have been studied in recent decades. Here, we report the results of a phase III trial conducted in Italy, which randomized patients with high-risk NMIBC to either surgery alone or surgery plus chemotherapy. The primary endpoint of the trial was disease progression-free survival (DPFS), defined as the time from randomization to disease progression or death. The study included 512 patients who were randomly assigned to one of three groups: surgery alone, surgery plus chemotherapy, or surgery plus therapy B (a combination of chemotherapy and immunotherapy). The results showed that surgery plus therapy B was associated with a statistically significant improvement in DPFS compared to surgery alone or surgery plus chemotherapy. The study also demonstrated that therapy B was well tolerated, with no major differences in adverse events between the groups. These findings suggest that therapy B may be a promising new treatment option for patients with high-risk NMIBC.