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Dose-dense methotrexate, vinblastine, doxorubicin and cisplatin (dd-MVAC) or gemcitabine and cisplatin (GC) as perioperative chemotherapy for patients with muscle-invasive bladder cancer (MIBC): Results of the GETUG/AFU VESPER V05 phase III trial

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Background

The optimal perioperative chemotherapy regimen for patients (pts) with MIBC is not defined.

Methods

Between February 2013 and February 2018, 500 pts were randomized in 28 French centres and received either 4 cycles of GC every 3 weeks or 6 cycles of dd-MVAC every 2 weeks before surgery (neoadjuvant group) or after surgery (adjuvant group). The primary endpoint of the VESPER trial was the progression-free survival (PFS) at 3 years (clinicaltrials.gov NCT 018 12369).

Results

437 patients (88%) received neoadjuvant chemotherapy, 60% of pts received the planned 6 cycles in the dd-MVAC arm and 84% received 4 cycles in the GC arm. Thereafter, 91% and 90% of pts underwent surgery, respectively. Organ-confined response (< ypT3N0) was observed more frequently in the dd-MVAC arm (77% vs 63%, $p=0.001$). In the adjuvant group, 40% of pts received 6 cycles in the dd-MVAC arm, 81% received 4 cycles in the GC arm. In the perioperative setting of the VESPER trial, PFS at 3 years was improved in the dd-MVAC arm (64% vs 56%, HR=0.77 (95% CI, 0.57-1.02), $p=0.066$), as was also time to progression (TTP) (3-year rate: 69% vs 58%, HR=0.68 (95% CI, 0.50-0.93), $p=0.014$). In the neoadjuvant group, the PFS at 3 years was significantly higher for the dd-MVAC arm (66% vs 56%, HR=0.70 (95% CI, 0.51-0.96), $p=0.025$). In the adjuvant group, the results were not conclusive due to the limited sample size ($n=56$).

Conclusions

In the VESPER phase III trial, we reported a benefit on PFS at 3 years for the dd-MVAC arm. In the neoadjuvant group, a better bladder tumour local control with a significant improvement on PFS at 3 years were observed in the dd-MVAC arm.

Clinical trial identification

NCT 018 12369.

Legal entity responsible for the study

The authors.

Funding

Grant from the French Ministry of Health (PHRC 2011-037).

Disclosure

All authors have declared no conflicts of interest.