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A trimodal therapeutic regimen developed in Japan has been reported to enable high-dose chemotherapy targeted specifically at the bladder, minimizing the toxic effects of systemic administration. In combination with transurethral resection of bladder tumour (TURBT) and radiotherapy, this methodology has produced high rates of recurrence-free complete response in patients with locally advanced cancer, as well as promising results in patients with lymph node metastases.

An ongoing aim in the treatment of bladder cancer is the development of strategies that avoid the morbidity associated with radical cystectomy, and that provide options for those patients who are not suitable candidates for cystectomy. To be accepted as true alternatives to cystectomy, new methods should be as good—or better—in terms of cancer recurrence and overall survival.

Haruhito Azuma and colleagues have developed a technique that uses double-balloon arterial occlusion to limit the blood supply to the bladder, such that intra-arterial infusion of chemotherapy (100–300 mg cisplatin) is targeted at the bladder, achieving high levels of tumour cytotoxicity. Systemic toxicity is prevented by concurrent haemodialysis of blood in the vena cava. Chemotherapy is administered 4–5 weeks after TURBT, and is followed by pelvic radiotherapy (60 Gy overall), with response assessed by transurethral resection at 6 weeks. This protocol ensured that “no patient suffered grade 2 or higher severe toxicities, and the oldest patient, aged 98 years, completed the therapy successfully,” explains Azuma.

Since 1988, this OMC (Osaka Medical College) regimen has been used to treat 329 patients. In the 267 patients with organ-confined disease $\leq T3$, 93.6% (250) achieved a complete response, and 96% (240 of 250) were recurrence-free with a functional bladder after a mean follow-up period of 159 weeks. The overall response rates were 83.6% complete response (276 of 329), 6.4% partial response (21 of 329) and 4.0% stable disease (13 of 329). Of the 54 patients who did not achieve complete response, three subsequently underwent total cystectomy and 18 had repeat OMC treatment using gemcitabine (with an additional complete response rate of 22%); the remaining patients are awaiting further treatment.

Among all 329 patients, 5-year and 10-year overall survival rates were 82.9% and 74.3%, respectively. Lymph node involvement, T4 stage, tumour histology and hydronephrosis were risk factors affecting overall survival. Despite this association, 5-year overall survival of patients with lymph node metastasis was 56%, and 61.9% of patients with stage N1 disease achieved a complete response, compared with 26.3% of patients with stage N2 disease.

“The OMC regimen can be regarded as a promising treatment for patients with organ-confined urothelial cancer, and a new option for patients with lymph node involvement, especially those at stage N1,” comments Azuma. “It will improve the feasibility of radical cure even without the need for cystectomy, and facilitate potential cure in patients for whom, otherwise, palliative treatment would seem the only option.”

Robert Phillips

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