Protocol for Planning and Treatment

The process to be followed when a course of chemotherapy is required to treat:

BLADDER CANCER

Patient information given at each stage following agreed information pathway

1. DIAGNOSIS

Bladder cancer is defined as cancer of the bladder urothelium (urachal adenocarcinoma is not covered by this protocol).

2. STAGING

All patents undergoing radical radiotherapy or surgery should have pre-operative imaging of chest and kidneys (Chest X-ray, ultrasound scan & IVU), with CT scanning of thorax, abdomen and pelvis, and/or MRI of pelvis prior to surgery. All patients should have cystoscopy and bladder biopsies or resection prior to definitive treatment to allow clinical staging according to the TNM system.

3. PATHOLOGY

Pathological reporting should include information on tumour type (urothelial carcinoma - transitional cell or squamous cell) differentiation (grade), staging (TNM), presence of muscle invasion, and for post-cystectomy specimen margins, nodal spread and perivesical fat invasion. Pathology and radiology should be available at the multidisciplinary meeting.

4. INVESTIGATIONS

Pre-chemotherapy calculation of creatinine clearance.

Utilise eGFR or 24 hour urine collection for creatinine clearance. Consider isotope renogram if concerns over renal function.

5. RADIOTHERAPY

Radical external beam conformal radiotherapy to bladder only (with salvage cystectomy for persistent/recurrent disease):
55Gy in 20fractions over 4 weeks (according to radiotherapy protocol with CT planning)

Post-cystectomy – whole pelvis radiotherapy (if residual or node +ve disease):
45Gy in 20fractions over 4 weeks

6. CHEMOTHERAPY

Neo-adjuvant Chemotherapy
Pre-operative neo-adjuvant chemotherapy is considered in selected patients with poor prognosis disease for whom radical treatment is still being contemplated (non-metastatic). Patients who have ureteric obstruction should be managed by nephrostomy placement or ureteric stenting prior to chemotherapy. Meta-analysis shows an overall absolute benefit of 5% for cisplatin-containing regimens, with benefit only in stage T3 patients (no benefit for stage T2), under 70 years of age and with GFR > 60 mls/min.

Adjuvant Chemotherapy
There is a lack of evidence base in order to recommend adjuvant chemotherapy as standard management for the majority of bladder cancer patients. Selected “high risk” patients may be considered for adjuvant chemotherapy (Level B evidence) if performance status 0-1, GFR > 60 and no significant co-morbidity.

Metastatic Disease
Those who have ureteric obstruction should be managed by nephrostomy placement, ureteric stenting or palliative urinary diversion procedures prior to chemotherapy.

Palliative Chemotherapy
Chemotherapy using a cisplatin-containing regimen should be considered for all patients with metastatic disease where general condition and renal function allow for its use, i.e. performance status 0 – 1, GFR > 60 mls/min.

“Unfit” patients: Poor risk factors are GFR 30-60, PS 2, and presence of visceral metastases. If all three risk factors are present there is no real benefit for chemotherapy vs. supportive care. Otherwise consider gemcitabine/carboplatin chemotherapy if only 1 risk factor i.e. low GFR, but performance status 0 – 1 and no visceral metastases.

7. TREATMENT DEFINITIONS

FIRST LINE: OPTIONS

GEMCITABINE/CISPLATIN
Cisplatin 80mg/m² IV Infusion Day 1
Gemcitabine 1250mg/m² IV Infusion Days 1 and 8

Repeated every 21 days for up to 6 cycles (3 cycles if neo-adjuvant chemotherapy)

M-VAC
Methotrexate 30mg/m² IV Bolus Days 1 and 15
Cisplatin 70mg/m² IV Infusion Day 2
Vinblastine 3mg/m² IV Bolus Days 2 and 15 (max dose 10mg)
Doxorubicin 30mg/m² IV Bolus Day 2

Repeated every 28 days for up to 6 cycles (3 cycles if neo-adjuvant chemotherapy)

First line option through patient and oncologist discussion
Medicine/formulation: Gem/Cis or M-VAC

"UNFIT" PATIENTS: OPTIONS

GEM/CARBO
Gemcitabine 1250mg/m² IV Infusion Days 1 and 8
Carboplatin AUC×5 (EDTA) or AUC×6 (Wright formula) IV Infusion Day 1

Repeated every 21 days for 4 - 6 cycles

Author: …… Signature: …….. Date: ……

Chair: …… Signature: …….. Date: ……
(on behalf of OHMMG)

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