

21.8.3. Documentation of Toxicity

(abbreviated version of Common Toxicity Criteria for documentation)

SIOP - LGG 2004

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Patient: _____ Date of birth: I _ I _ I.I _ I _ I.I _ I _ I ID-Nr. _____

Please complete for every course of chemotherapy:

<input type="checkbox"/> Induction Vincristin/Carboplatin	<input type="checkbox"/> Consolidation Vincristin/Carboplatin	week: I _ I _ I
<input type="checkbox"/> Induction Vincristin/Carboplatin/Etoposide	<input type="checkbox"/> Consolidation Vincristin/Cisplatin	from I _ I _ I..I _ I _ I..I _ I
	<input type="checkbox"/> Consolidation Vincristin/Cyclophosphamide	to I _ I _ I..I _ I _ I..I _ I

Please tick the appropriate field for each parameter (maximal toxicity). For more details see addendum 21.11.

Degree of toxicity	0	I	II	III	IV
Blood					
Hemoglobin (g/l)	WNL	<LLN - 100	80 - <100	65 - <80	< 65
Leukocytes (mm ³)	WNL	<LLN - 3000	≥2000 - <2000	1000 - <2000	< 1000
Granulocytes (mm ³)	WNL	<LLN - 1500	≥1000 - <1500	≥500 - <1000	< 500
Platelets (mm ³)	WNL	<LLN - 75000	≥50000 - <75000	≥10000 - <50000	< 10000
Auditory/Hearing					
Inner ear / hearing	normal	hearing loss on audiometry only	Tinnitus	Tinnitus, correctable with hearing aid	severe hearing loss, not correctable
Bilateral hearing loss (Brock et al, 1991)	< 40 dB at all frequencies	> 40 dB at 8000 Hz only	> 40 dB at 4000 Hz only	> 40 dB at 2000 Hz only	> 40 dB at 1000 Hz only
Neurology					
Neuropathy-cranial	absent	-	present, not interfering with activities	present, interfering with activities	life-threatening, disabling
Neuropathy-motor	normal	subjective weakness	mild objective weakness	objective weakness	paralysis
Neuropathy-sensory	normal	loss of deep tendon reflexes or paresthesia	objective sensory loss or paresthesia	functionally relevant sensory loss or paresthesia	permanent sensory loss that interferes with function
Seizure(s)	non	-	seizure(s) self-limited, consciousness preserved	seizure(s) with altered consciousness	Prolonged seizure(s) of any type (e.g. status epilepticus)
Abdominal pain or cramping	non	mild pain, not interfering with function	moderate pain not interfering with activities	severe pain interfering with activities of daily living	disabling
Infection					
Infection	none	mild	moderate	severe	life-threatening, septic shock
Fever	non	38,0 - 39,0°C	39,1 - 40,0 °C	> 40 °C for < 24 h	> 40°C for > 24 h
Renal					
Hematuria	none	microscopic only	intermittent gross bleeding, no clots	persistent gross bleeding or clots	open surgery or necrosis or deep bladder ulceration
Creatinine (x ULN)	WNL	>ULN - 1,5	> 1,5 - 3,0	> 3,0 - 6,0	> 6,0
Proteinuria (g/24 hrs)	normal or < 0,15	1+ or 0,15-1,0	2+ to 3+; 1,0-3,5	4+ ; > 3,5	nephrotic syndrome
Creatinine-clearance (ml/min + 1,73 m ²)	≥ 90	60 - 89	40 - 59	20 - 39	≤ 19
Nausea/Vomiting					
Nausea	none	Nausea, but still able to eat	oral intake significantly decreased	no significant intake, requiring IV fluids	-
Vomiting (number of episodes/24 h)	none	1	1-5	≥ 6	requiring parenteral nutrition
Constitutional Symptoms					
Weight loss	< 5%	5% - < 10%	10% - <20%	≥ 20%	-
Anorexia	none	loss of appetite	oral intake significantly decreased	requiring IV fluids	requiring feeding tube or parenteral nutrition

Patient: _____

Alopecia	normal	mild hair loss	pronounced hair loss	-	-
Fatigue	none	increased fatigue over baseline	moderate, causing difficulty	Severe, loss of ability to perform some activities	bedridden or disabling
Allergic reaction / hypersensitivity	none	transient rash, drug fever < 38°C	urticaria, drug fever ≥ 38°C and/or asymptomatic brochospasm	symptomatic brochospasm with or without urticaria, allergy-related edema/angioedema	anaphylaxis
Gastrointestinal					
Mucositis	none	eythema of the mucosa	patchy pseudo-membranous reaction	confluent pseudo-membranous reaction	necrosis or deep ulceration; bleeding not induced by minor trauma or abrasion
Stomatitis/Pharyngitis	none	painless ulcers, erythema or mild soreness in the absence of lesions	painful erythema, edema or ulcers, but can eat or swallow	painful erythema, edema or ulcers requiring IV hydration	severe ulceration or requires parenteral or enteral nutritional support or prophylactic intubation
Diarrhea	none	increase of <4 stools/day over pre-treatment	increase of 4-6 stools/day or nocturnal stools	increase of ≥7 stools/day or incontinence requiring IV hydration	physiologic consequences requiring intensive care or hemodynamic collapse
Constipation	none	requiring stool softener or dietary modification	requiring laxatives	obstipation requiring manual evacuation or enema	obstruction or toxic megacolon
Dermatology/Skin					
Radiation dermatitis	none	faint erythema or dry desquamation	moderate to brisk erythema or patchy moist desquamation, confined to skin folds and creases; moderate edema	confluent moist desquamation ≥1,5 cm diameter and not confined to skin folds; pitting edema	skin necrosis or ulceration of full thickness dermis; may include bleeding not induced by minor trauma or abrasion
Hepatic					
Bilirubin (xULN)	WNL	> ULN - 1,5	> 1,5 - 3,0	> 3,0 - 10,0	> 10,0
SGOT/SGPT (xULN)	WNL	> ULN - 2,5	> 2,5 - 5,0	> 5,0 - 20,0	> 20,0
Pulmonary					
Dyspnea	normal	-	dyspnea on exertion	dyspnea at normal leves of activity	dyspnea at rest or requiring ventilator support
Cardiovascular					
Cardiac left ventricular function	normal	asymptomatic decline of resting ejection fraction of ≥ 10% but <20% of baseline value; shortening fraction ≥ 24% but <30%	asymptomatic, but resting ejection fraction below LLN for laboratory or decline of resting ejection fraction ≥20% of baseline value; <24% shortening fraction	CHF responsive to treatment	severe or refractory CHF or requiring intubation
LV-EF Echocardiography	> 30%	26% - 30%	21% - 25%	16% - 20%	< 16%

Date _____

Stamp _____

Signature _____