

がん臨床試験の評価項目 - 有害事象の評価 -

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臨床試験の指標

QOL
症状緩和効果（疼痛）
主観的副作用、有害事象
客観的副作用、有害事象
腫瘍縮小
再発
死亡

ソフト



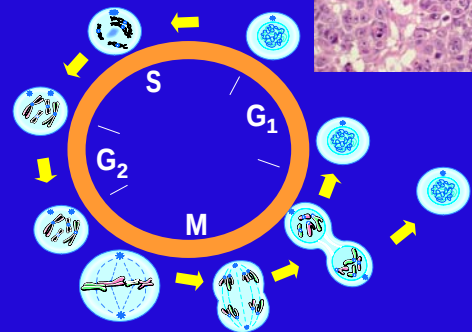
ハード

有害物質である抗がん剤

Cytotoxic Chemotherapy : 細胞毒性化学療法

DNA合成、RNA合成、紡錘糸合成など、細胞分裂のプロセスを阻害するため、癌細胞のみならず、正常細胞にも障害を及ぼす。

細胞分裂と細胞周期



毒性の評価

第I相試験	どんな毒性がでるか、どの程度にでるのか、皆目検討がつかない状況で評価する。
第II相試験	ある程度検討は付くが、思いもよらない毒性が出現する可能性もある。
第III相試験	思いもよらない毒性が出現することは少ない事前に毒性を絞り込んで評価することもある。
第IV相試験	実臨床での毒性の頻度、程度を確認する。特殊な対象（肝、腎機能低下症例など）での毒性を評価することもある。

用語について（1）

ICH; Guideline on Clinical Safety Data Management

有害事象 (Adverse Event : AE)

薬剤が投与された患者（被験者）に生じたあらゆる好ましくない医療上のできごと、薬剤との因果関係の有無は問わない。

薬物有害反応 (Adverse Drug Reaction : ADR)

通常の投与量で生じるすべての有害かつ意図しない、薬剤に対する反応。因果関係がある、または因果関係が否定できないもの。

用語について (2)

ICH; Guideline on Clinical Safety Data Management

副作用 (Side Effect)

薬剤の主作用以外の作用を指す。

→ 害でも益でも関係なく用いられており、紛らわしい。

毒性 (Toxicity)

薬剤の有害な影響の総称であり因果関係を論ずる必要のない状況で用いられる。

一般薬と抗がん剤

一般薬

治療比 > 1

発現被験者数

効果 副作用

投与量

抗がん剤

治療比 ≤ 1

発現被験者数

効果

副作用

投与量

毒性記載様式の統一 抗がん剤の場合

NCI - CTC (version 2.0)

(National Cancer Institute - Common Toxicity Criteria)

- 抗がん剤毒性を評価、記録、報告する規準として世界的に定着
- 毒性を 24のカテゴリーに分類
- 個々の毒性の程度を gradeで表現
- 日本語版も出版されている
(NCI-CTC日本語訳JCOG版-第2版; 癌と化療 28:1993, 2001)

Common Terminology Criteria for Adverse Events v3.0 (CTCAE)

Publish Date: December 12, 2003

Quick Reference

The NCI Common Terminology Criteria for Adverse Events (CTCAE) v3.0 is a descriptive terminology which can be utilized for Adverse Event (AE) reporting. A grading (severity) scale is provided for each AE term.

Components and Organization

CATEGORY

A CATEGORY is a broad classification of AEs based on anatomy and/or pathophysiology. Within each CATEGORY, AEs are listed according to their descriptions of severity (Grade).

Adverse Event Terms

An AE is any unfavorable and unintended sign (including abnormal laboratory findings, symptoms, or disease) temporally associated with the use of a medical treatment or procedure that may or may not still be considered related to the medical treatment or procedure. An AE is a term that is a unique representation of a specific event used for medical documentation and scientific analysis. Each AE term is mapped to a MedDRA term and each AE term is listed alphabetically within CATEGORIES.

Short AE Names

The "Short form" column is new and it is used to simplify documentation of AE names on Case Report Forms.

Supra-ordinate Terms

A supra-ordinate term is located within a CATEGORY and is a grouping term based on disease process, signs, symptoms,

or diagnosis. A supra-ordinate term is followed by the word "and" and is accompanied by specific AEs that are all related to the supra-ordinate term. Supra-ordinate terms provide grouping and hierarchical representation of Grades for adverse events and clinical events. Supra-ordinate terms are not AEs, are not mapped to a MedDRA term and code, cannot be graded and cannot be used for reporting.

REMARK

A REMARK is a classification of an AE.

ALSO CONSIDER

An "Also Consider" indicates additional AEs that are to be graded if they are clinically significant.

NAMING CONVENTION

A NAMING CONVENTION indicates the location of an AE term within the CTCAE document. It lists signs/symptoms alphabetically and the CTCAE term will appear in the same CATEGORY unless the NAMING CONVENTION states otherwise.

Grades

Grades refer to the severity of the AE. The CTCAE v3.0 defines Grades 1 through 5 with unique clinical descriptions of severity for each AE listed on this general guideline.

Grade 1: Mild AE
Grade 2: Moderate AE
Grade 3: Severe AE
Grade 4: Life-threatening or disabling AE
Grade 5: Death related to AE

A term colon indicates "or" within the description of the grade. An "Or dash" (--) indicates a grade not available.

Not all Grades are appropriate for all AEs. Therefore, some AEs are listed with fewer than five options for Grade selection.

Grade 5 (Death) is not appropriate for some AEs and therefore is not an option.

The DEATH CATEGORY is new. Only one Supra-ordinate term is listed in this CATEGORY. Death not associated with CTCAE term -- Death -- with a AE option. Death NOT. Death associated with CTCAE term. Death death. Death death.

Grade 5 is the only appropriate Grade.

This AE is to be used in the situation where a death.

1. cannot be reported using a CTCAE v3.0 term associated with Grade 5 or

2. cannot be reported within a CTCAE CATEGORY as Other (Specify).

ALLERGY/IMMUNOLOGY.....1	HEMORRHAGE/BLEEDING.....30	SEXUAL/REPRODUCTIVE FUNCTION.....64
AUDITORY/EAR.....2	HEPATOBLILIARY/PANCREAS.....34	SURGERY/INTRA-OPERATIVE INJURY.....66
BLOOD/ BONE MARROW.....4	INFECTION.....35	SYNDROMES.....68
CARDIAC ARRHYTHMIA.....6	LYMPHATICS.....38	VASCULAR.....70
CARDIAC GENERAL.....7	METABOLIC/LABORATORY.....40	
COAGULATION.....10	MUSCULOSKELETAL/SOFT TISSUE.....42	
CONSTITUTIONAL SYMPTOMS.....11	NEUROLOGY.....47	
DEATH.....13	OCULAR/VISUAL.....52	
DERMATOLOGY/SKIN.....14	PAIN.....55	
ENDOCRINE.....17	PULMONARY/UPPER RESPIRATORY.....56	
GASTROINTESTINAL.....19	RENALE/GENITOURINARY.....60	

有害事象の評価と記載方法

NCI-CTC v2.0

(Common Toxicity Criteria v2.0)



NCI-CTCAE v3.0

(Common Terminology Criteria for Adverse Events v3.0)

Categories of CTCAE v3.0

- | | |
|----------------------------|--------------------------------------|
| 1. Allergy/Immunology | 15. Infection |
| 2. Auditory/EAR | 16. Lymphatic |
| 3. Blood/Bone Marrow | 17. Metabolic/Laboratory |
| 4. Cardiac Arrhythmia | 18. Musculoskeletal/Soft Tissue |
| 5. Cardiac General | 19. Neurology |
| 6. Coagulation | 20. Ocular/Visual |
| 7. Constitutional Symptoms | 21. Pain |
| 8. Death | 22. Pulmonary/Upper respiratory |
| 9. Dermatology/Skin | 23. Renal/Genitourinary |
| 10. Endocrine | 24. Secondary Malignancy |
| 11. Gastrointestinal | 25. Sexual/Reproductive Function |
| 12. Growth and Development | 26. Surgery/Intra-operational Injury |
| 13. Hemorrhage/Bleeding | 27. Syndromes |
| 14. Hepatobiliary/Pancreas | 28. Vascular |

Grade of CTCAE v3.0

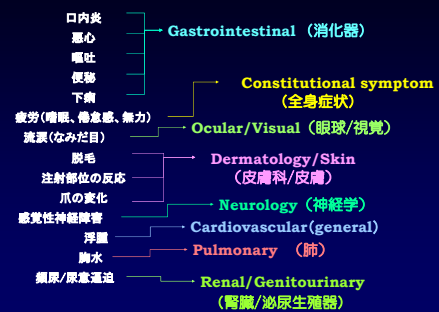
- Grade 1 Mild AE
- Grade 2 Moderate AE
- Grade 3 Severe AE
- Grade 4 Life-threatening or disabling AE
- Grade 5 Death related to AE

Grade of CTCAE v3.0

- Grade 1 軽い AE
- Grade 2 中程度の AE
- Grade 3 激しい、耐え難い AE
- Grade 4 生命を脅かすまたは何もできない程の AE
- Grade 5 AEに関連した死亡

抗がん剤の副作用として多いもの

- | | |
|---------|-------|
| むかむかする | 下痢する |
| 吐く | 過敏性反応 |
| 髪の毛が抜ける | 好中球減少 |
| 熱がでる | 鼻血 |
| 口内炎 | 間質性肺炎 |
| むくみ | 呼吸困難 |
| しびれ | 難聴 |



むかむかする

II
nausea

GASTROINTESTINAL

GASTROINTESTINAL							Page 6 of 10	
Adverse Event		Short Name		Grade				
				1	2	3	4	5
Mucositis/stomatitis (clinical exam)		Mucositis (clinical exam) - Sore		Erythema of the mucosa	Patchy ulcerations or pseudomembranes	Confluent ulcerations or pseudomembranes	Tissue necrosis, significant spontaneous bleeding, or death	Death
- Anus								
- Esophagus								
- Large bowel								
- Larynx								
- Oral cavity								
- Pharynx								
- Rectum								
- Small bowel								
- Stomach								
- Trachea								
Reflux, Mucositis/stomatitis (symptoms/signs) may be seen.								
Mucositis/stomatitis (clinical exam)		Mucositis (clinical exam)		Upper aerodigestive tract			Lower aerodigestive tract	
- Sore		- Sore		Upper aerodigestive tract			Lower aerodigestive tract	
- Anus		- Anus		Upper aerodigestive tract			Lower aerodigestive tract	
- Esophagus		- Esophagus		Upper aerodigestive tract			Lower aerodigestive tract	
- Large bowel		- Large bowel		Upper aerodigestive tract			Lower aerodigestive tract	
- Larynx		- Larynx		Upper aerodigestive tract			Lower aerodigestive tract	
- Oral cavity		- Oral cavity		Upper aerodigestive tract			Lower aerodigestive tract	
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- Large bowel		- Large bowel		Upper aerodigestive tract			Lower aerodigestive tract	
- Larynx		- Larynx		Upper aerodigestive tract			Lower aerodigestive tract	
- Oral cavity		- Oral cavity		Upper aerodigestive tract			Lower aerodigestive tract	
- Pharynx		- Pharynx		Upper aerodigestive tract			Lower aerodigestive tract	
- Rectum		- Rectum		Upper aerodigestive tract			Lower aerodigestive tract	
- Small bowel		- Small bowel		Upper aerodigestive tract			Lower aerodigestive tract	
- Stomach		- Stomach		Upper aerodigestive tract			Lower aerodigestive tract	
- Trachea		- Trachea		Upper aerodigestive tract			Lower aerodigestive tract	
Reflux, Mucositis/stomatitis (symptoms/signs) may be seen.								
Mucositis/stomatitis (clinical exam)		Mucositis (clinical exam)		Upper aerodigestive tract			Lower aerodigestive tract	
- Sore		- Sore		Upper aerodigestive tract			Lower aerodigestive tract	
- Anus		- Anus		Upper aerodigestive tract			Lower aerodigestive tract	
- Esophagus		- Esophagus		Upper aerodigestive tract			Lower aerodigestive tract	
- Large bowel		- Large bowel		Upper aerodigestive tract			Lower aerodigestive tract	
- Larynx		- Larynx		Upper aerodigestive tract			Lower aerodigestive tract	
- Oral cavity		- Oral cavity		Upper aerodigestive tract			Lower aerodigestive tract	
- Pharynx		- Pharynx		Upper aerodigestive tract			Lower aerodigestive tract	
- Rectum		- Rectum		Upper aerodigestive tract			Lower aerodigestive tract	
- Small bowel		- Small bowel		Upper aerodigestive tract			Lower aerodigestive tract	
- Stomach		- Stomach		Upper aerodigestive tract			Lower aerodigestive tract	
- Trachea		- Trachea		Upper aerodigestive tract			Lower aerodigestive tract	
Reflux, Mucositis/stomatitis (symptoms/signs) may be seen.								
Mucositis/stomatitis (clinical exam)		Mucositis (clinical exam)		Upper aerodigestive tract			Lower aerodigestive tract	
- Sore		- Sore		Upper aerodigestive tract			Lower aerodigestive tract	
- Anus		- Anus		Upper aerodigestive tract			Lower aerodigestive tract	
- Esophagus		- Esophagus		Upper aerodigestive tract			Lower aerodigestive tract	
- Large bowel		- Large bowel		Upper aerodigestive tract			Lower aerodigestive tract	
- Larynx		- Larynx		Upper aerodigestive tract			Lower aerodigestive tract	
- Oral cavity		- Oral cavity		Upper aerodigestive tract			Lower aerodigestive tract	
- Pharynx		- Pharynx		Upper aerodigestive tract			Lower aerodigestive tract	
- Rectum		- Rectum		Upper aerodigestive tract			Lower aerodigestive tract	
- Small bowel		- Small bowel		Upper aerodigestive tract			Lower aerodigestive tract	
- Stomach		- Stomach		Upper aerodigestive tract			Lower aerodigestive tract	
- Trachea		- Trachea		Upper aerodigestive tract			Lower aerodigestive tract	
Reflux, Mucositis/stomatitis (symptoms/signs) may be seen.								
Mucositis/stomatitis (clinical exam)		Mucositis (clinical exam)		Upper aerodigestive tract			Lower aerodigestive tract	
- Sore		- Sore		Upper aerodigestive tract			Lower aerodigestive tract	
- Anus		- Anus		Upper aerodigestive tract			Lower aerodigestive tract	
- Esophagus		- Esophagus		Upper aerodigestive tract			Lower aerodigestive tract	
- Large bowel		- Large bowel		Upper aerodigestive tract			Lower aerodigestive tract	
- Larynx		- Larynx		Upper aerodigestive tract			Lower aerodigestive tract	
- Oral cavity		- Oral cavity		Upper aerodigestive tract			Lower aerodigestive tract	
- Pharynx		- Pharynx		Upper aerodigestive tract			Lower aerodigestive tract	
- Rectum		- Rectum		Upper aerodigestive tract			Lower aerodigestive tract	
- Small bowel		- Small bowel		Upper aerodigestive tract			Lower aerodigestive tract	
- Stomach		- Stomach		Upper aerodigestive tract			Lower aerodigestive tract	
- Trachea		- Trachea		Upper aerodigestive tract			Lower aerodigestive tract	
Reflux, Mucositis/stomatitis (symptoms/signs) may be seen.								
Mucositis/stomatitis (clinical exam)		Mucositis (clinical exam)		Upper aerodigestive tract			Lower aerodigestive tract	
- Sore		- Sore		Upper aerodigestive tract			Lower aerodigestive tract	
- Anus		- Anus		Upper				

吐く

II
vomiting



GASTROINTESTINAL

髪の毛が抜ける

II
hair loss



DERMATOLOGY/SKIN

DERMATOLOGY/SKIN					
Adverse Event		Short Name		Grade	
		1	2	3	4
Atrophy, skin	Atrophy, skin	Detectable	Marked	---	---
Atrophy, subcutaneous	Atrophy, subcutaneous	Detectable	Marked	---	---
Auto-Condition: Induration/flexion (skin and subcutaneous tissue)					
Brusling (in absence of Grade 3 or 4 Brunsley/epidermal)	Brusling	Localized or in a dependent area	Generalized	---	---
Burn	Burn	Minimal symptoms; intervention not indicated	Medical intervention; minimal disturbance indicated	Moderate to major disturbance or reconstruction indicated	Life-threatening consequences
Rashes: (burn refers to all burns including radiation, chemical, etc.)					
Cheilitis	Cheilitis	Asymptomatic	Symptomatic, not interfering with ADL	Symptomatic, interfering with ADL	---
Dry skin	Dry skin	Asymptomatic	Symptomatic, not interfering with ADL	Interfering with ADL	---
Flushing	Flushing	Asymptomatic	Symptomatic	---	---
Hair loss (alopecia) (body or body)	Alopecia	Thinning or patchy	Complete	---	---
Hypopigmentation	Hypopigmentation	Slight or localized	Marked or generalized	---	---
Hypopigmentation	Hypopigmentation	Slight or localized	Marked or generalized	---	---
Induration/flexion (skin and subcutaneous tissue)	Induration	Increased density on palpation	Moderate impairment of function; not interfering with ADL; marked increase in density and thickness on palpation with or without minimal traction	Dysfunction interfering with ADL; very marked density; initiation or friction	---
Auto-Condition: Fibrosis-contracture; Fibrosis deep connective tissue					
Injection site reaction/ extravasation changes	Injection site reaction	Pain, itching, erythema	Pain or swelling, with inflammation or phlebitis	Ulceration or necrosis that is severe; operative intervention indicated	---
Auto-Condition: Allergic reaction/hypersensitivity (including drug fever); Liberation					

熱がでる

II
fever



CONSTITUTIONAL SYMPTOMS
(全身症状)

CONSTITUTIONAL SYMPTOMS					
Adverse Event		Short Name		Grade	
		1	2	3	4
Fatigue (asthenia, lethargy, malaise)	Fatigue	Mild fatigue over baseline	Moderate or causing difficulty performing some ADL	Severe fatigue interfering with ADL	Disabling
Fever (in the absence of neutropenia, where neutropenia is defined as ANC <1.0 x 10 ⁹ /L)	Fever	38.0 - 39.0°C (100.4 - 102.2°F)	>39.0 - 40.0°C (102.2 - 104.0°F)	>40.0°C (>104.0°F) for >24 hrs	>40.0°C (>104.0°F) for >24 hrs
Reactive: The temperature measurements listed are oral or tympanic. Also Consider: Allergic reaction/hypersensitivity (including drug fever).					
Navigation Note: Hot flashes are graded as Hot flashes/flushes in the ENDOCRINE CATEGORY.					
Hypothermia	Hypothermia	---	35 - 32°C (95 - 89.6°F)	32 - 28°C (89.6 - 82.4°F)	<28 °C (82.4°F or life-threatening consequences (e.g., coma, hypotension, pulmonary edema, acidosis, ventricular fibrillation)
Insomnia	Insomnia	Occasional difficulty sleeping, not interfering with function	Difficulty sleeping, interfering with function but not interfering with ADL	Frequent difficulty sleeping, interfering with ADL	Disabling
Reactive: If pain or other symptoms interfere with sleep, do NOT grade as insomnia. Grade primary event(s) causing insomnia.					
Obesity	Obesity	---	BMI 25 - 29.9 kg/m ²	BMI 30 - 39.9 kg/m ²	BMI ≥40 kg/m ²
Reactive: BMI = (weight [kg]) / (height [m]) ²					
Odor (patient odor)	Patient odor	Mild odor	Pronounced odor	---	---
Rigors/chills	Rigors/chills	Mild	Moderate, narcotics indicated	Severe or prolonged, not responsive to narcotics	---

口内炎



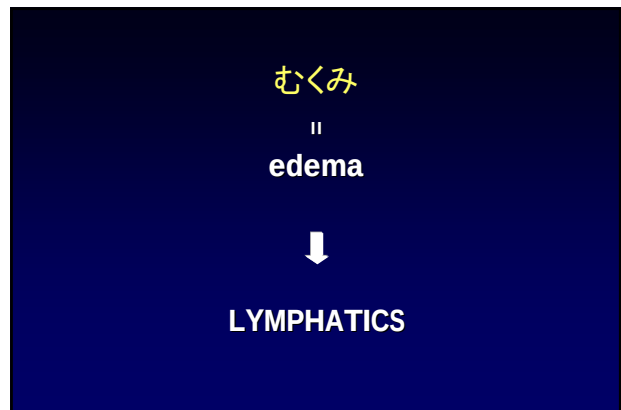
粘膜炎

II
Mucositis



GASTROINTESTINAL

GASTROINTESTINAL						Page 6 of 10
		Grade				
Adverse Event	Short Name	1	2	3	4	5
Mucositis/stomatitis (clinical exam) – Select: – Anus – Esophagus – Large bowel – Larynx – Oral cavity – Pharynx – Rectum – Small bowel – Stomach – Trachea	Mucositis (clinical exam) – Select	Erythema of the mucosa	Patchy ulcerations or pseudomembranes	Confluent ulcerations or pseudomembranes, bleeding with minor trauma	Tissue necrosis, significant spontaneous bleeding, life-threatening consequences	Death
Reuser: Mucositis/stomatitis (functional/symptomatic) may be used for mucositis of the upper aero-digestive tract caused by radiation, agents, or GVHD.						
Mucositis/stomatitis (functional/symptomatic) – Select: – Anus – Esophagus – Large bowel – Larynx – Oral cavity – Pharynx – Rectum – Small bowel – Stomach – Trachea	Mucositis (functional/symptomatic) – Select	Upper aerodigestive tract sites: Minimal symptoms, normal diet; minimal respiratory symptoms but not interfering with function Lower GI sites: Minimal discomfort, intervention not indicated	Upper aerodigestive tract sites: Symptomatic but can eat and swallow modified diet; respiratory symptoms interfering with function but not interfering with ADL Lower GI sites: Symptomatic, medical intervention indicated but not interfering with ADL	Upper aerodigestive tract sites: Symptomatic and unable to adequately aliment or hydrate orally; respiratory symptoms interfering with ADL Lower GI sites: Stool incontinence or other symptoms interfering with ADL	Symptoms associated with life-threatening consequences	Death
Nausea	Nausea	Loss of appetite without alteration in eating habits	Oral intake decreased without significant weight loss, dehydration or malnutrition; IV fluids indicated <24 hrs	Inadequate oral caloric or fluid intake; IV fluids, tube feedings, or TPN indicated <24 hrs	Life-threatening consequences	Death
Also Consider: Anorexia, Vomiting						



LYMPHATICS						Page 1 of 2
Adverse Event	Short Name	1	2	3	4	5
Chyle or lymph leakage	Chyle or lymph leakage	Asymptomatic, clinical or radiographic findings	Symptomatic, medical intervention indicated	Interventional radiology or operative intervention indicated	Life-threatening complications	Death
Also Consider: Chylothorax						
Dermal change lymphedema, phlebotomolymphedema	Dermal change	Trace thickening or faint discoloration	Marked discoloration; leathery skin texture; scaly keratosis	—	—	—
Reuser: Dermal change lymphedema, phlebotomolymphedema refers to changes due to venous stasis						
Also Consider: Ulceration						
Edema: head and neck	Edema: head and neck	Localized to dependent areas, no functional impairment	Localized facial or neck edema with functional impairment	Generalized facial or neck edema with functional impairment (e.g., difficulty in turning neck or opening mouth compared to baseline)	Severe with ulceration or central edema; tracheostomy or feeding tube indicated	Death
Edema: limb	Edema: limb	5 – 10% inter limb discrepancy in volume or circumference at point of greatest swelling or discoloration of anatomic architecture on close inspection; pitting edema	>10 – 20% inter limb discrepancy in volume or circumference at point of greatest swelling or discoloration of anatomic architecture; discoloration of skin folds; readily apparent deviation from normal anatomic contour	>20% inter limb discrepancy in volume; lymphedema, gross deviation from normal anatomic contour; interfering with ADL	Progression to malignancy (i.e., lymphangiosarcoma); amputation indicated; disabling	Death
Edema: trunk/genital	Edema: trunk/genital	Swelling or discoloration of anatomic architecture on close inspection; pitting edema	Readily apparent discoloration of anatomic architecture; discoloration of skin folds; readily apparent deviation from normal anatomic contour	Lymphedema, interfering with ADL; gross deviation from normal anatomic contour	Progression to malignancy (i.e., lymphangiosarcoma); disabling	Death
Edema: viscera	Edema: viscera	Asymptomatic; clinical or radiographic findings only	Symptomatic; medical intervention indicated	Symptomatic and unable to aliment adequately orally; interventional radiology or operative intervention indicated	Life-threatening consequences	Death



NEUROLOGY						Page 4 of 5
Adverse Event		Grade				
Adverse Event	Short Name	1	2	3	4	5
Neuropathy: cranial – Select: – CN I: Small – CN II: Vision – CN III: Pupils, upper eyelids, extra ocular movements – CN IV: Oculomotor, inward movement of eyes – CN V: Motor (jaw muscles); Sensory (facial) – CN VI: Lateral deviation of eyes – CN VII: Motor (face); Sensory (taste) – CN VIII: Hearing and balance – CN IX: Motor (pharynx); Sensory (ear, pharynx, tongue) – CN X: Motor (palate, pharynx, larynx) – CN XI: Motor (diaphragm) and trapezius – CN XII: Motor (tongue)	Neuropathy: cranial – Select	Asymptomatic, detected on examination only	Symptomatic, not interfering with ADL	Symptomatic, interfering with ADL	Life-threatening; disabling	Death
Neuropathy: motor	Neuropathy: motor	Asymptomatic, weakness on examination only	Symptomatic weakness interfering with function, but not interfering with ADL	Weakness interfering with ADL, bracing or assistance to walk (e.g., cane or walker) indicated	Life-threatening; disabling	Death
Reuser: Cranial nerve <u>motor</u> neuropathy is graded as Neuropathy: cranial – Select.						
Also Consider: Laryngeal nerve dysfunction; Phrenic nerve dysfunction						
Neuropathy: sensory	Neuropathy: sensory	Asymptomatic; loss of deep tendon reflexes or paresthesia (including tingling) but not interfering with function	Sensory alteration or paresthesia (including tingling), interfering with function, but not interfering with ADL	Sensory alteration or paresthesia interfering with ADL	Disabling	Death
Reuser: Cranial nerve <u>sensory</u> neuropathy is graded as Neuropathy: cranial – Select						
Personality/behavioral	Personality	Change, but not adversely affecting patient or family	Change, adversely affecting patient or family	Mental health intervention indicated	Change harmful to others or self; hospitalization indicated	Death
Phrenic nerve dysfunction	Phrenic nerve	Asymptomatic; weakness on examination only	Symptomatic, but not interfering with ADL; intervention not indicated	Significant dysfunction; intervention indicated (e.g., tracheostomy, ventilation)	Life-threatening; respiratory compromise; mechanical ventilation indicated	Death
Psychosis (hallucinations/ delusions)	Psychosis	—	Transient episode	Interfering with ADL, medication, supervision or restraints indicated	Harmful to others or self; life-threatening consequences	Death



GASTROINTESTINAL					
Adverse Event		Grade			
Adverse Event	Short Name	1	2	3	4
Dental: periodontal disease	Periodontal	Gingival recession or gingivitis, limited bleeding on probing, mild local bone loss	Moderate gingival recession or gingivitis, multiple sites of bleeding on probing, moderate bone loss	Spontaneous bleeding, severe bone loss with or without tooth loss, osteomyelitis of maxilla or mandible	---
Remarks: Severe periodontal disease leading to osteomyelitis is graded as Osteomyelitis (vascular necrosis) in the MUSCULOSKELETAL CATEGORY. Also Co-occur: Dehydration, hypotension.					
Dental: tooth	Tooth	Surface stains, dental caries, restorable, without extractions	Less than full-mouth extractions, tooth fracture or crown amputation or repair indicated	Full-mouth extractions indicated	---
Dental: tooth development	Tooth development	Hypoplasia of tooth or enamel not interfering with function	Functional impairment compatible with oral surgery	Maldevelopment with functional impairment not surgically correctable	---
Diarrhea	Diarrhea	Increase of >1 stool per day over baseline, mild increase in ostomy output compared to baseline	Increase of 4 - 8 stools per day over baseline, IV fluids indicated <24 hrs, moderate increase in ostomy output compared to baseline, not interfering with ADL	Increase of >7 stools per day over baseline, IV fluids indicated <24 hrs, hospitalization, severe increase in ostomy output compared to baseline, interfering with ADL	Life-threatening consequences (e.g., hemodynamic collapse)
Remarks: Diarrhea includes diarrhea of small bowel or colonic origin, and/or ostomy diarrhea. Also Co-occur: Dehydration, hypotension.					
Distension/bloating, abdominal	Distension	Asymptomatic	Symptomatic, but not interfering with GI function	Symptomatic, interfering with GI function	---
Also Co-occur: Asiles (non-malignant), Bow, GI (functional obstruction of bowel, i.e., neuromuscular), Distension, GI - Severe.					

過敏性反応

II

Hypersensitivity Reaction (HSR)



ALLERGY/IMMUNOLOGY

ALLERGY/IMMUNOLOGY					
Adverse Event		Grade			
Adverse Event	Short Name	1	2	3	4
Allergic reaction/hypersensitivity (including drug fever)	Allergic reaction	Transient flushing or rash, drug fever $>38.3^{\circ}\text{C}$ ($>101.4^{\circ}\text{F}$)	Rash, flushing, urticaria, dyspnea, drug fever $>39^{\circ}\text{C}$ ($>102.4^{\circ}\text{F}$)	Symptomatic bronchospasm, with or without urticaria, epinephrine medication(s) indicated, allergic-related edema/hypotension	Anaphylaxis
Remarks: Urticaria with manifestations of allergic or hypersensitivity reaction is graded as Allergic reaction/hypersensitivity (including drug fever). Also Co-occur: Cytokine release syndrome, infusion reaction.					
Allergic rhinitis (including sneezing, nasal stuffiness, postnasal drip)	Rhinitis	Mild, intervention not indicated	Moderate, intervention indicated	---	---
Remarks: Rhinitis associated with obstruction or atresia is graded as Obstruction/atresia of airway - Severe in the PULMONARY/RESPIRATORY CATEGORY.					
Autoimmune reaction	Autoimmune reaction	Asymptomatic and/or evidence of autoimmune reaction, with normal organ function and intervention not indicated	Evidence of autoimmune reaction involving a non-essential organ or function (e.g., thyroiditis)	Reversible autoimmune reaction involving function of a major organ or other adverse event (e.g., transient colitis or anemia)	Autoimmune reaction with life-threatening consequences
Also Co-occur: Colitis, Hemoglobin, Hemolysis (e.g., immune hemolytic anemia, drug-related hemolysis), Thyroid function, low (hypothyroidism).					
Serum sickness	Serum sickness	---	---	Present	Death
Remarks: Norm: Spleen function is graded in the BLOOD/BONE MARROW CATEGORY. Remarks: Norm: Urticaria as an isolated symptom is graded as Urticaria (flashes, welts, wheals) in the DERMATOLOGY/SKIN CATEGORY.					
Vasculitis	Vasculitis	Mild, intervention not indicated	Symptomatic, non-essential medical intervention indicated	Severe indicated	Ischemic changes, amputation indicated
Allergy/immunology - Other (Specify: ...)	Allergy - Other (Specify: ...)	Mild	Moderate	Severe	Life-threatening, disabling

好中球減少

II

neutrocytopenia



BLOOD/BONE MARROW

BLOOD/BONE MARROW					
Adverse Event		Grade			
Adverse Event	Short Name	1	2	3	4
Bone marrow cellularity	Bone marrow cellularity	Mildly hypocellular or $>20\%$ reduction from normal cellularity for age	Moderately hypocellular or $>20\%$ reduction from normal cellularity for age	Severely hypocellular or $>50\%$ reduction from normal cellularity for age	---
CD4 count	CD4 count	$<400 - 500/\text{mm}^3$ $<4.0 \times 10^6/\text{L}$	$<200 - 250/\text{mm}^3$ $<0.2 - 0.25 \times 10^6/\text{L}$	$<100 - 150/\text{mm}^3$ $<0.1 - 0.15 \times 10^6/\text{L}$	Death
Hemoglobin	Hemoglobin	$<10\text{g}$	$<8\text{g}$	Absent	Death
Hematocrit	Hematocrit	$<30\%$	$<20\%$	$<10\%$	Death
Hemolysis (e.g., immune hemolytic anemia, drug-related hemolysis)	Hemolysis	Laboratory evidence of hemolysis only (e.g., direct antiglobulin test (DAT, Coombs) subtypes)	Evidence of red cell destruction and $>2\text{ gm}$ decrease in hemoglobin, no transfusion	Transfusion or medical intervention (e.g., steroids) indicated	Catastrophic consequences of hemolysis (e.g., renal failure, hypotension, bronchospasm, emergency splenectomy)
Also Co-occur: Hemoglobin, Hemolysis.					
Iron overload	Iron overload	---	Asymptomatic iron overload, intervention not indicated	Iron overload, intervention indicated	Organ impairment (e.g., endocrinopathy, cardiomyopathy)
Leukocytes (total WBC)	Leukocytes	$<1000 - 3000/\text{mm}^3$ $<1.0 - 3.0 \times 10^6/\text{L}$	$<500 - 1000/\text{mm}^3$ $<0.5 - 1.0 \times 10^6/\text{L}$	$<200 - 500/\text{mm}^3$ $<0.2 - 0.5 \times 10^6/\text{L}$	Death
Lymphopenia	Lymphopenia	$<1000 - 2000/\text{mm}^3$ $<1.0 - 2.0 \times 10^6/\text{L}$	$<500 - 1000/\text{mm}^3$ $<0.5 - 1.0 \times 10^6/\text{L}$	$<200 - 500/\text{mm}^3$ $<0.2 - 0.5 \times 10^6/\text{L}$	Death
Myelodysplasia	Myelodysplasia	---	---	Abnormal marrow cytogenetics (non-blast $>5\%$)	RAEB or RAEB-T (myeloid blasts $>5\%$)
Neutrophils/granulocytes (ANCs)	Neutrophils	$<1000 - 1500/\text{mm}^3$ $<1.0 - 1.5 \times 10^6/\text{L}$	$<500 - 1000/\text{mm}^3$ $<0.5 - 1.0 \times 10^6/\text{L}$	$<200 - 500/\text{mm}^3$ $<0.2 - 0.5 \times 10^6/\text{L}$	Death
Platelets	Platelets	$<75,000 - 100,000/\text{mm}^3$ $<75 - 100 \times 10^9/\text{L}$	$<50,000 - 75,000/\text{mm}^3$ $<50 - 75 \times 10^9/\text{L}$	$<25,000 - 50,000/\text{mm}^3$ $<25 - 50 \times 10^9/\text{L}$	Death
Spleen function	Spleen function	Incidental findings (e.g., Howell-Jolly bodies)	Phagocytosis antibodies indicated	---	Life-threatening consequences
Blood/Bone Marrow - Other (Specify: ...)	Blood - Other (Specify: ...)	Mild	Moderate	Severe	Life-threatening, disabling

鼻血

II

Nasal bleeding



HEMORRHAGE/BLEEDING

間質性肺炎

II

Interstitial Pneumonitis

↓

PULMONARY/UPPER RESPIRATORY

呼吸困難

II

Dyspnea

↓

PULMONARY/UPPER RESPIRATORY

難聴

II

Hearing loss

↓

AUDITORY/EAR

AUDITORY/EAR					
Adverse Event		Grade			
Short Name		1	2	3	4
Neurotoxicity: Ototoxicity (otitis) is graded as Part - Select in the PART CATEGORY.					
Hearing patterns without baseline audiogram and enrolled in a monitoring program?	Hearing (without monitoring program)	Threshold shift or loss of 15 - 25 dB relative to baseline, averaged at 2 or more contiguous test frequencies in at least one ear; or subjective change in the absence of a Grade 1 threshold shift	Threshold shift or loss of >25 - 50 dB, averaged at 2 contiguous test frequencies in at least one ear	Adult only: Threshold shift of >50 - 90 dB, averaged at 3 contiguous test frequencies in at least one ear Pediatric: Hearing loss sufficient to initiate therapeutic intervention, including hearing aids (e.g., <25 dB bilateral HL in the speech frequency, <35 dB unilateral HL, and requiring additional speech-language related services)	Adult only: Profound bilateral hearing loss (>90 dB) Pediatric: Audiologic indication for cochlear implant and requiring additional speech-language related services
Notes: Pediatric recommendations are identical to those for adults, unless specified. For children and adolescents (<18 years of age) without a baseline test, pre-exposure/pre-treatment hearing should be considered to be <5 dB loss.					
Hearing patterns without baseline audiogram and not enrolled in a monitoring program?	Hearing (without monitoring program)	---	Hearing loss not requiring hearing aid or intervention (i.e., not interfering with ADL)	Hearing loss requiring hearing aid or intervention (i.e., interfering with ADL)	Profound bilateral hearing loss (>90 dB)
Notes: Pediatric recommendations are identical to those for adults, unless specified. For children and adolescents (<18 years of age) without a baseline test, pre-exposure/pre-treatment hearing should be considered to be <5 dB loss.					
Otitis, external ear (non-infectious)	Otitis, external	External otitis with erythema or dry desquamation	External otitis with moist desquamation, edema, enhanced cerumen or discharge, tympanic membrane perforation, tympanostomy	External otitis with mastoiditis, stenosis or osteomyelitis	Necrosis of soft tissue or bone
Also Consider: Hearing: patients without baseline audiogram and enrolled in a monitoring program?; Hearing: patients without baseline audiogram and not enrolled in a monitoring program?					
Otitis, middle ear (non-infectious)	Otitis, middle	Serous otitis	Serous otitis, medical intervention indicated	Otitis with discharge, mastoiditis	Necrosis of the canal soft tissue or bone
Death					

副作用に関する患者の意識

抗がん剤の副作用は投与数日後に現われる。薬剤はその間ずっと体内にとどまっている。

抗がん剤の副作用が軽いので効果もない。

副作用は薬でおさえるより我慢する方が効果が強い。

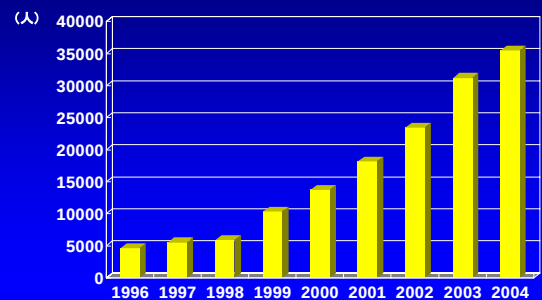
抗がん剤は入院して投与の方が外来でするより安全である。

• • • • •

抗がん剤治療の安全性に関するいくつかの疑問

- 抗がん剤は入院して投与する方が安全か？
いいえ、外来でも十分に安全に実施できます。
- 安全に抗がん剤治療を行うために採血検査は必要か？
- 採血検査のタイミングは？
 - 点滴実施日
 - 点滴と点滴との間の白血球（好中球）が減少する時期
 投与開始前に1回実施しておけばそれで十分です。
- 抗がん剤治療で最も注意する時期はいつか？
初回投与直後、各投与終了後

国立がんセンターにおける外来化学療法総数（のべ数）



なぜ外来化学療法が増えているのか

- 有効性の高い薬剤が使えるようになってきた
→ アンソサイクリン系、プラチナ系、タキサン系
- 化学療法の重要性、必要性が認識されてきた
- 短時間で投与できる薬剤が増えてきた
→ シスプラチン → カルボプラチン
→ 持続点滴 → 数時間の点滴
→ シュアフューザーの利用
- 副作用対策が進歩した
→ 5-HT₃ブロッカー、G-CSF、経口抗生剤

なぜ外来化学療法が増えているのか

- QOLを重視する考え方が普及してきた
- 入院が安全ということもないという認識の普及
- 病院のあり方が変わってきた
→ 収容施設→療養施設→診療施設
- 仕事をしながら治療をする患者の増加

なぜ外来化学療法が増えているのか

- 総医療費抑制策
- 入院期間の短縮、入院比率の低減
- 病院・診療所連携推進
 - 在宅中の診療支援
- 情報技術の進歩（携帯電話、電子メール）
 - 在宅・病院、患者・医師

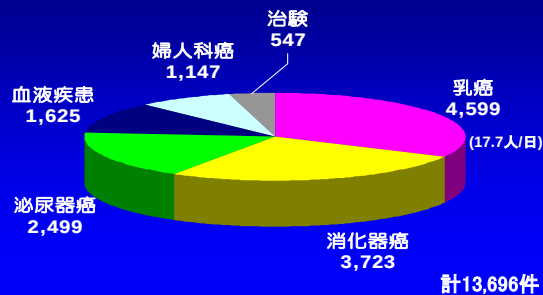
がん薬物療法の効果

- A 治癒が期待できる
 睾丸腫瘍、急性白血病、非ホジキンリンパ腫（中・高悪性度）
 ホジキン病、絨毛癌
- B 延命が期待できる
 乳癌、卵巣癌、小細胞肺癌、多発性骨髄腫、慢性骨髄性白血病非ホジキンリンパ腫（低悪性度）
- C QOL改善が期待できる
 非小細胞肺癌、食道癌、胃癌、大腸癌、肝癌、前立腺癌、頭頸部癌
 軟部組織肉腫、骨肉腫、膀胱癌、子宮頸癌、子宮体癌
- D 効果は不十分
 脳腫瘍、悪性黒色腫、腎癌、肝癌、甲状腺癌

がん診療レジデントマニュアル（第3版） 医学書院

疾患別化学療法の患者の割合

国立がんセンター中央病院 2000年度



化学療法に対する行政誘導

(1) 平成15年4月より包括医療費導入 大学病院、国立がんセンターなどの特定機能病院

DRG（診断群別分類）・PPS（診断群別包括支払い方式）
 (Diagnosis Related Groups / Prospective Payment System)

癌治療：入院39,400円/日(6日まで)、化学療法は包括対象、手術は対象外。

実際、化学療法はいくらかかるの？

身長 160cm、体重 55kg、体表面積 1.6m² の場合

Epirubicin 75mg/m²
 Cyclophosphamide 600 mg/m²

薬品名	使用量	単価	単位	薬価（円）
塩酸ファルモルピシン	120mg	7,591	10 mg	91,092
注射用エンドキサン	960mg	1,023	500 mg	2,046
デカドロン	20mg	224	4 mg	1,120
注射用カイトリル	3mg	7,988	3 mg	7,988
合計				102,246

実際、化学療法はいくらかかるの？

身長 160cm、体重 55 kg、体表面積 1.6m² の場合

Herceptin 4mg/kg
 Taxol 80 mg/m²

薬品名	使用量	単価	単位	薬価（円）
ハーセプチン注射用	220mg	80,042	150 mg	160,084
タキソール注	128mg	47,370	100mg	47,370
		16,164	30mg	16,164
ザンタック	50mg	209	50 mg	209
クロルトリメトン	10mg	97	10 mg	97
デカドロン	8 mg	224	4 mg	448
合計				224,372

化学療法に対する行政誘導

(2) 平成14年度診療報酬改定「外来化学療法加算」新設

「別に厚生労働大臣が定める**施設基準**に適合するものとして地方社会保険事務局長に届け出た保険医療機関において、入院中の患者以外の患者であって、悪性腫瘍の患者であるものに対して化学療法を行った場合は、外来化学療法加算として、1日につき、300点を加算する」

外来化学療法加算の施設基準

平成16年度の改定で、日本医療機能評価機構の機能評価を受けていること、という要件が施設基準から削除された。これによって診療所での算定も可能となった。

- (1) 外来化学療法を行うにつき必要な体制が整備されていること
- (2) 外来化学療法を行うにつき必要な機器および十分な専用施設を有していること

外来化学療法加算の施設基準

- (1) 外来化学療法を実施するための**専用の病床**(点滴注射による化学療法を実施するために適したリクライニングシートを含む)を有する治療室を保有していること。なお、外来化学療法を実施している間は、当該治療室を外来化学療法その他の点滴注射（輸血を含む）以外の目的で使用することは認められない。
- (2) 化学療法の経験を有する**専任の常勤看護師**が当該治療室に勤務していること。点滴は看護師が行う。
- (3) 当該化学療法につき**専任の常勤薬剤師**が勤務していること。
- (4) 急変時等の緊急時に当該患者が入院できる体制が確保されていること又は他の保険医療機関との連携により緊急時に当該患者が入院できる体制が整備されていること。

次回の講義

- 最終講義 -

これからの癌治療