MANAGING CHEMOTHERAPY SIDE EFFECTS

REVIEWING PREVENTION AND TREATMENT STRATEGIES OF THREE COMMON ISSUES

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OBJECTIVES

- Identify tactics for preventing and treating acute infusion reactions
- Describe non-pharmacological and pharmacological ways to prevent or manage chemotherapy induced peripheral neuropathy
- Demonstrate an understanding of cancer-related fatigue and treatable contributing factors

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INFUSION RELATED REACTION (IRR) HYPERSENSITIVITY REACTION (HSR)

Acute (<1 hour)

- Pruritis (itching)
- Flushing
- Urticaria (hives)
- Dyspnea
- Bronchospasm
- Chest pain/tightness
- Fever
- Rigors or chills
- Hypo- or hypertension
- Back pain

Ann Oncol. 2012;23 Suppl 10:x312-x319

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MEDICATIONS COMMONLY ASSOCIATED WITH ACUTE INFUSION REACTIONS

- TAXANES
  - PACLITAXEL (TAXOL®)
  - NAB-PACLITAXEL (ABRAXANE®)
  - DOCETAXEL (TAXOTERE®)
- PLATINUM-BASED
  - CISPLATIN (PLATINOL®)
  - CARBOPLATIN (PARAPLATIN®)
  - OXALIPLATIN (ELOXATIN®)
- CETUXIMAB (ERIBITUX®)
- RITUXIMAB (RITUXAN®)

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INFUSION RELATED REACTIONS (IRR) SUBTYPES

Type I
- Ige mediated
- Associated with repeated exposure
- Release of histamine, prostaglandins, leukotrienes
- Contraction of smooth muscle and dilation of capillaries
- Urticaria, hypotension, rash, bronchospasm

Anaphylactoid or Pseudoallergy
- First or second exposure
- Direct interaction with mast cells and basophils
- Cytokine release
- Hypotension, rash, bronchospasm

Oncologist. 2007;12(5):601-609

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COMMON TERMINOLOGY CRITERIA FOR ADVERSE EVENTS (CTCAE) VERSION 5.0

CTCAE Term	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Infusion related reaction	Mild transient reaction; infusion interruption not indicated; intervention not indicated	Therapy or infusion interruption indicated but responds promptly to symptomatic treatment (e.g., antihistamines, NSAIDS, narcotics, IV fluids); prophylactic medications indicated for <=24 hrs	Prolonged (e.g., not rapidly responsive to symptomatic medication and/or brief interruption of infusion); recurrence of symptoms following initial improvement; hospitalization indicated for clinical sequelae	Life-threatening consequences; urgent intervention indicated	Death
Definition: A disorder characterized by adverse reaction to the infusion of pharmacological or biological substances.					

Common Terminology Criteria for Adverse Events (CTCAE) v5.0. Publish Date: November 27, 2017

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EXAMPLE OF EMERGENCY ORDER SET

NURSING OXYGEN ORDERS / INSTRUCTIONS- OXYGEN DEVICE: NASAL CANNULA LITERS PER / MINUTE: 2 KEEP SPO2 > OR = TO: 92 FOR GRADE 2 - MODERATE SYMPTOMS AND GRADE 3 - SEVERE/ANAPHYLAXIS SYMPTOMS

SODIUM CHLORIDE (NS) 0.9 % INFUSION 20 ML/HR, INTRAVENOUS- FOR GRADE 1 - MILD SYMPTOMS OR GRADE 2 - MODERATE SYMPTOMS

SODIUM CHLORIDE 0.9% (NS BOLUS) BOLUS 1,000 ML- FOR GRADE 3 - SEVERE/ANAPHYLAXIS SYMPTOMS.

DIPHENHYDRAMINE (BENADRYL) INJECTION 25 MG 25 MG, INTRAVENOUS, ONCE AS NEEDED, FOR GRADE 1 - MILD SYMPTOMS, GRADE 2 - MODERATE SYMPTOMS, OR GRADE 3 - SEVERE/ANAPHYLAXIS SYMPTOMS.,

FAMOTIDINE IV 20 MG- FOR GRADE 2 - MODERATE SYMPTOMS OR GRADE 3 - SEVERE/ANAPHYLAXIS SYMPTOMS.

MEPERIDINE (DEMEROL) INJECTION 25 MG- ONCE AS NEEDED, RIGORS, STARTING WHEN RELEASED, FOR 1 DOSE FOR GRADE 1 - MILD SYMPTOMS OR GRADE 2 - MODERATE SYMPTOMS

METHYLPREDNISOLONE SODIUM SUCCINATE INJECTION 125 MG- 125 MG, INTRAVENOUS, ONCE AS NEEDED, FOR GRADE 2 - MODERATE SYMPTOMS OR GRADE 3 - SEVERE/ANAPHYLAXIS SYMPTOMS.

EPINEPHRINE IM 0.3 MG- 0.3 MG, INTRAMUSCULAR, ONCE AS NEEDED, FOR GRADE 3 - SEVERE/ANAPHYLAXIS SYMPTOMS

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TAXANES

PACLITAXEL (TAXOL®)	NAB-PACLITAXEL (ABRAXANE®)	DOCETAXEL (TAXOTERE®)
SOLVENT: CREMEPHOR EL (POLYOXYL 35/POLYOXYETHYLATED CASTOR OIL) PREMEDICATION: H1 BLOCKER, CORTICOSTEROID, H2 BLOCKER RATE OF HSR: 31-45%; SEVERE: 2-4% CROSS REACTIVITY: ??	SOLVENT: N/A PREMEDICATION: NO PREMEDICATION IS REQUIRED RATE OF HSR: 4% CROSS REACTIVITY: RARE	SOLVENT: POLYSORBATE 80 (TWEEN 80) PREMEDICATION: CORTICOSTEROID FOR 3 DAYS; DEXAMETHASONE 8 MG TWICE DAILY, BEGIN DAY BEFORE INFUSION RATE OF HSR: 6-21% CROSS REACTIVITY: ??

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PACLITAXEL (AND DOCETAXEL): RE-CHALLENGE

- INCREASE CORTICOSTEROIDS
  - DEXAMETHASONE 20 MG PO 12 HOURS AND 6 HOURS PRIOR
- INCREASE ANTIHISTAMINES
- SLOW INFUSION RATE
  - 50% OF USUAL RATE
  - TITRATION

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TOLERANCE OF NAB-PACLITAXEL

37 patients	All doses appropriately premedicated	Nab-paclitaxel
• 31 history of paclitaxel HSR • 6 history of paclitaxel and docetaxel hsr	• Paclitaxel- Dexamethasone 20mg iv, diphenhydramine 50 mg iv, famotidine 20 mg iv (30 minutes before) • Docetaxel- dexamethasone 20 mg po (evening before and morning of), diphenhydramine 50 mg iv, famotidine 20 mg iv (30 minutes before)	• Dexamethasone 10 mg iv (30 minutes before) first 3 infusions • Dexamethasone omitted unless needed for nausea prevention • No HSRs

J Gynecol Oncol. 2017;28(6):e38

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PLATINUM-BASED CHEMOTHERAPIES AND HSRS

- PRIMARILY IGE MEDIATED
- OCCURRENCE INCREASES WITH INCREASED EXPOSURE
- INCREASE IN SEVERITY
- NOT IMMEDIATELY RESPONSIVE TO TREATMENT

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RITUXIMAB

Dermatologic	• Pruritis ≤ 17% • Urticaria 2-8%
Respiratory	• Dyspnea 7-10% • Bronchospasm 8%
Cardiovascular	• Flushing 5-14% • Hypertension 6-12% • Hypotension 10% • Chest tightness 7%
Other	• Angioedema 11% • Rigors 10%

Rituximab (intravenous) including biosimilars of rituximab: Drug Information LexiComp.In: UpToDate. Waltham, Mass.: UpToDate, 2020. www.uptodate.com. Accessed August 1,2020.

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RITUXIMAB

Patient Characteristic Influencing HSR

- Bulky disease > 10 cm
- Indolent subtypes (eg, mantle cell lymphoma (MCL), follicular lymphoma (FL))
- High levels of circulating tumor B-cells

Strategies for Managing HSR

- Interrupt infusion
- Give medications (antihistamines or corticosteroids)
- Restart at 50% rate
- Titrate ???

Int J Clin Pharm. 2017 Apr;39(2):280-283
J Allergy Clin Immunol Pract. Sep-Oct 2018;6(5):1621-1627.e4

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CETUXIMAB (ERBITUX®)

- EGFR receptor antagonist used in head neck cancer and metastatic colorectal cancers
- Initial FDA approval had grade ¾ infusion reaction in < 5% of patients
- Southwestern United States (including North Carolina and Tennesee) saw grade ¾ reactions of >20%
- Preformed immunoglobulin E antibodies against galactose-α-1,3-galactose in serum

Cancer. 2016 Jun 1;122(11):697-701. doi: 10.1002/cncr.29978. Epub 2016 Mar 15
https://expt.lilly.com/erbitux/erbitux.html#s18.

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CETUXIMAB

Alpha-gal assay for IgE antibodies

- Negative = < 0.10 kU/L
- Included levels up to <0.35 kU/L

61.7% (37/60) patients negative

- Values: <0.10-0.23 kU/L
- No anaphylaxis

38.3% (23/60) patients positive

- Values: <1.0-44.2
- Excluded from cetuximab arm

Alpha-gal testing not mandated in package insert

- Evaluate for history of tick bites
- History of red meat allergy

Send out test

- 7 days for results

Premedicate

- Antihistamines
- Corticosteroids

Cancer. 2016 Jun 1;122(11):697-701.
https://expt.lilly.com/erbitux/erbitux.html#s18.

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RAPID DRUG DESENSITIZATION

- ONE SOLUTION DESENSITIZATION
  - TOTAL DOSE PREPARED
  - 500 ML TOTAL VOLUME- PLATINES, TAXANES, RITUXIMAB
  - 250 ML FOR CETUXIMAB
- PREMEDICATIONS
  - CETIRIZINE 10 MG ORAL (PO)- (EVERY 12 HOURS SINCE 3 DAYS BEFORE)
  - ASPIRIN 200-500 MG PO - (EVERY 24 HOURS SINCE DAY BEFORE, UNLESS CONTRAINDICATION)
  - MONTELUKAST 10 MG PO - (EVERY 24 HOURS SINCE DAY BEFORE)
  - DEXCHLORPHENIRAMINE 5 MG IV – (30 MINUTES BEFORE)
  - RANITIDINE 50 MG IV – (30 MINUTES BEFORE)
  - METHYLPREDNISILONE 1 MG/KG IV OR HYDROCORTISONE 100 MG IV FOR RITUXIMAB
  - DEXAMETHASONE 20 MG PO (12 HOURS AND 1 HOUR BEFORE)

J Allergy Clin Immunol Pract. 2018;6(5):1621:1627.e6.

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RAPID DRUG DESENSITIZATION

Example of dosing for 130 mg of oxaliplatin diluted in 525 mL of volume (0.247 mg/mL)

Rate (mL/hr)	Time (min)	Accumulated Time (min)	Volume (mL)	Accumulated Volume (mL)	Dose (mg)	Accumulated Dose (mg)
5	15	15	1.25	1.25	0.3	0.3
10	15	30	2.5	3.75	0.68	0.98
25	15	45	6.25	10	1.54	2.52
50	15	60	12.5	22.5	3.08	5.6
75	15	75	18.75	41.25	4.63	10.23
100	15	90	25	66.25	6.17	16.4
150	15	105	37.5	103.75	9.26	25.66
200	15	120	50	153.75	12.35	38.01
250	89.16	209.16	371.5	525	91.76	129.77

J Allergy Clin Immunol Pract. 2018;6(5):1621:1627.e6

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TAKE HOME POINTS

- HYPERSENSITIVITY REACTIONS/INFUSION RELATED REACTIONS ARE UNPREDICTABLE
- PREDICTING IRRS MAY BE POSSIBLE IN CETUXIMAB AND RITUXIMAB
- HAVE STANDING HSR RESPONSE ORDERS IN PLACE
- CONSIDER ENHANCED PREMEDICATION STRATEGIES AND SLOWER INFUSION RATES
- DISCONTINUE PRECIPITATING MEDICATION
- CHANGE TREATMENT WHERE APPROPRIATE
- CONSIDER DESENSITIZATION WHEN DISCONTINUATION OR CHANGING TREATMENT NOT OPTION AND/OR EXPECTED FUTURE TREATMENTS ARE LIMITED

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CHEMOTHERAPY INDUCED PERIPHERAL NEUROPATHY (CIPN)

RECOMMENDATIONS FOR PREVENTION AND TREATMENT

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CHEMOTHERAPY AGENTS ASSOCIATED WITH PERIPHERAL NEUROPATHY

- TAXANES
- PLATINUMS
- VINCA ALKALOIDS
- ERIBULIN
- BORTEZOMIB/CARFILZOMIB

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PREVENTION AND MANAGEMENT OF CHEMOTHERAPY-INDUCED PERIPHERAL NEUROPATHY IN SURVIVORS OF ADULT CANCERS: AMERICAN SOCIETY OF CLINICAL ONCOLOGY (ASCO) GUIDELINE UPDATE

- PACLITAXEL MYALGIAS AND ARTHRALGIAS RECLASSIFIED AS ACUTE NEUROPATHY
- TOTAL CHEMOTHERAPY EXPOSURE ONLY RECOMMENDED PREVENTION STRATEGY

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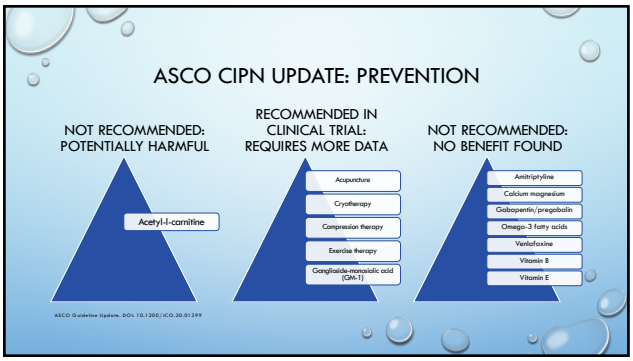
ASCO CIPN UPDATE: PREVENTION
NOT RECOMMENDED: POTENTIALLY HARMFUL
Acetyl-l-carnitine
RECOMMENDED IN CLINICAL TRIAL: REQUIRES MORE DATA
Acupuncture
Cryotherapy
Compression therapy
Exercise therapy
Ganglioside-monosialic acid (GM-1)
NOT RECOMMENDED: NO BENEFIT FOUND
Amitriptyline
Calcium magnesium
Gabapentin/pregabalin
Omega-3 fatty acids
Venlafaxine
Vitamin B
Vitamin E
ASCO Guideline Update. DOI: 10.1200/JCO.20.01399

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CRYOTHERAPY
KEEPING HANDS AND FEET COLD DURING CHEMOTHERAPY ADMINISTRATION

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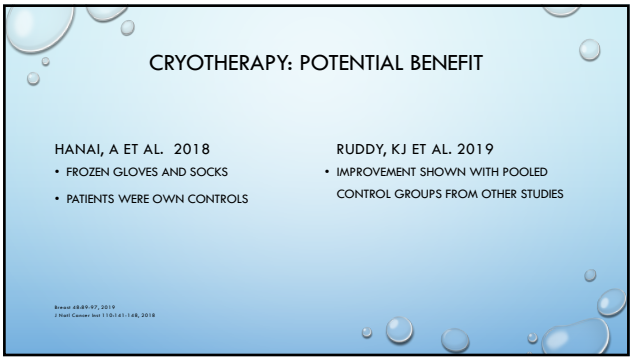
CRYOTHERAPY: POTENTIAL BENEFIT
HANAI, A ET AL. 2018
• FROZEN GLOVES AND SOCKS
• PATIENTS WERE OWN CONTROLS
RUDDY, KJ ET AL. 2019
• IMPROVEMENT SHOWN WITH POOLED CONTROL GROUPS FROM OTHER STUDIES
Breast 68:89-97, 2019
J Natl Cancer Inst 110:1:61-148, 2018

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ASCO TREATMENT RECOMMENDATIONS

For painful neuropathy
- Duloxetine

Not recommended outside of clinical trial
- Exercise therapy
- Acupuncture
- Scrambler therapy
- Gabapentin/pregabalin
- Topical gel treatment containing baclofen, amitriptyline HCL, plus/minus ketamine
- Tricyclic antidepressants
- Oral cannabinoids

ASCO Guideline Update. DOI: 10.1200/JCO.20.01399

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TRICYCLIC ANTIDEPRESSANTS

- Amitriptyline, nortriptyline, desipramine and imipramine
- Moved from: "reasonable to try" to "not recommended"
- Lack of evidence for efficacy in treating CIPN
- No new clinical trials since last update
- Unfavorable side effects: drowsiness, irregular heart rate, confusion in older patients

ASCO Guideline Update. DOI: 10.1200/JCO.20.01399

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GABAPENTINOIDS
GABAPENTIN AND PREGABALIN

- Evidence for treating established CIPN is inconclusive
- More clinical trials required before routine use endorsed by ASCO
- Some insurance companies require failed trial of gabapentinoid before duloxetine

ASCO Guideline Update. DOI: 10.1200/JCO.20.01399

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PREGABALIN VERSUS DULOXETINE

BREAST CANCER PATIENTS TREATED WITH PACLITAXEL OR DOCETAXEL

Pregabalin
- 75 mg once daily x 1 week
- 150 mg twice daily x 5 weeks
- N=40
- Visual analog scale (VAS) scores improved in 37/40 (92.5%)

Duloxetine
- 30 mg once daily x 1 week
- 30 mg twice daily x 5 weeks
- N=42
- Visual analog scale (VAS) scores improved in 16/42 (38.1%)

Salehifar E et al. Clin Drug Investig. 2020 Mar;40(3):249-257. doi: 10.1007/s40261-019-00882-6.
Arora R et al. J Rev Med Sci. 2018;23:32. doi: 10.1016/j.jsrp.2017.11.013

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DULOXETINE FOR PAINFUL CIPN

PATIENTS WHO COMPLETED CHEMOTHERAPY WITH PACLITAXEL OR OXALIPLATIN

231 patients randomized
↓
Randomized, double-blind, placebo-controlled crossover
↓
≥ grade 1 CIPN and ≥ 4/10 neuropathy-related pain
↓
Symptoms persisting for at least 3 months since chemotherapy completion
↓
Duloxetine 30 mg once daily then 60 mg once daily for 4 weeks
↓
2 week washout then cross over

JAMA. 2013;309(13):1359-1367

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CANCER – RELATED FATIGUE

CANCER-RELATED FATIGUE IS A DISTRESSING, PERSISTENT, SUBJECTIVE SENSE OF PHYSICAL, EMOTIONAL, AND/OR COGNITIVE TIREDNESS OR EXHAUSTION RELATED TO CANCER OR CANCER TREATMENT THAT IS NOT PROPORTIONAL TO RECENT ACTIVITY AND INTERFERES WITH USUAL FUNCTIONING.

NCCN Guidelines. Cancer-Related Fatigue.Version 2.2020.May 4, 2020.

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EVALUATING AND ASSESSING FATIGUE

CTCAE Term	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Fatigue	Fatigue relieved by rest	Fatigue not relieved by rest; limiting instrumental ADL	Fatigue not relived by rest; limiting self care ADL	----	----
	Definition: A disorder characterized by a state of generalized weakness with a pronounced inability to summon sufficient energy to accomplish daily activities.				

Common Terminology Criteria for Adverse Events (CTCAE) v5.0

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EVALUATING AND ASSESSING FATIGUE

- SCALE OF 1-10
  - 0= NO FATIGUE AND 10= WORST FATIGUE YOU CAN IMAGINE
  - 0-3= NONE TO MILD
  - 4-6= MODERATE
  - 7-10= SEVERE
- DESCRIPTION
  - NONE
  - MILD
  - MODERATE
  - SEVERE

NCCN Guidelines. Cancer-Related Fatigue.Version 2.2020.May 6, 2020.

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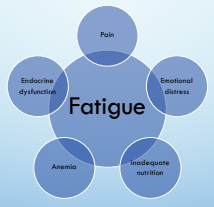
IDENTIFY AND TREAT UNDERLYING CAUSES



NCCN Guidelines. Cancer-Related Fatigue.Version 2.2020.May 6, 2020.

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INADEQUATE NUTRITION

NUTRITION CONSULT
PHARMACY
NURSING SUPPORT

- Nausea or vomiting
- Dysgeusia
- Loss of appetite
- Constipation
- Diarrhea
- Mucositis
- Gerd

NCCN Guidelines. Cancer-Related Fatigue,Version 2.2020,May 4, 2020.

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PAIN AND EMOTIONAL DISTRESS

- Insomnia
- Sleep interruptions
- Side effects of medication
- Reduced activity

NCCN Guidelines. Cancer-Related Fatigue,Version 2.2020,May 4, 2020.

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ANEMIA AND ENDOCRINE DISTURBANCES

- ANEMIA
  - IRON REPLACEMENT
  - TRANSFUSION
- HYPOTHYROIDISM
  - REPLACEMENT
- ADRENAL INSUFFICIENCY
- HYPOGONADISM
- HOT FLASHES

NCCN Guidelines. Cancer-Related Fatigue,Version 2.2020,May 4, 2020

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NON-PHARMACOLOGICAL INTERVENTIONS

Sleep Hygiene

Avoid caffeine/nicotine in late afternoon	Consistent schedule	Avoid bright light in evenings	Turn off electronics 30 minutes before	Eat light at night

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NON-PHARMACOLOGICAL INTERVENTIONS

Physical activity
- Walk 30 minutes most days of the week
- Cardiovascular endurance
- Resistance training

Yoga
- Twice weekly

Patient Specific Considerations
- Bone metastasis
- Thrombocytopenia/anemia
- Recent surgery
- Safety issues (e.g. falling)

NCCN Guidelines, Cancer-Related Fatigue,Version 2.2020,May 6, 2020.

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PHARMACOLOGICAL INTERVENTIONS

Methylphenidate
- Active treatment
- Advanced cancer
- End of life

Corticosteroids
- Short term use
- Advanced cancer

Nutritional supplements
- Inconclusive

Modafinil
- Not recommended

Antidepressants
- Not recommended

NCCN Guidelines, Cancer-Related Fatigue,Version 2.2020,May 6, 2020.

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METHYLPHENIDATE

- USE WITH CAUTION
- FIRST RULE OUT AND TREAT UNDERLYING CAUSES
- SHOWS IMPROVEMENT IN FATIGUE COMPARED TO PLACEBO
- OPTIMAL DOSING IN CANCER PATIENTS AND OLDER ADULTS NOT ESTABLISHED
  - METHYLPHENIDATE 5 MG TO 36 MG DAILY IN TRIALS
  - METHYLPHENIDATE 5 MG ONCE DAILY STARTING DOSE
- SIDE EFFECTS
  - HEADACHE
  - NAUSEA

Cancer Care (Engl). 2016;35(6):970-979
NCCN Guidelines. Cancer-Related Fatigue Version 2.2020.May 4, 2020
J Clin Oncol. 2010 Aug 10;28(23):3673-9

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