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Cachexia

Abstract PA-01
Patients With Cancer Cachexia Benefit From Multidisciplinary Team Management

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BACKGROUND: Cancer cachexia occurs in approximately one third of newly diagnosed cancer patients. Unaddressed, cancer cachexia may result in delayed, missed, or decreased treatments. An aggressive, multidisciplinary team approach may result in fewer hospital days, fewer missed treatments, and improved outcomes. METHODS: The Palliative Care Program of a cancer center developed a 9-month pilot project to address cancer cachexia through a multidisciplinary clinic. High-risk populations were identified. The clinic team included a physician, a nurse practitioner, a registered dietitian, a physical therapist, and a speech therapist. During visits, the patient received medical, nutritional, speech, and physical therapy evaluations followed by an individualized care plan. Outcomes were measured by symptom measurement scales, quality-of-life (QOL) instruments (Edmonton Symptom Assessment System, Functional Assessment of Anorexia/Cachexia Therapy), nutritional, and functional parameters. The goal was to assess the impact of an interdisciplinary approach on symptom management, nutrition, function, and QOL. RESULTS: A total of 55 patients were included in the pilot period. Eleven patients had four visits or more, where the greatest benefit was seen. At four or more clinic visits, Karnofsky Performance Status, body cell mass, weight, appetite, and fatigue improved from the first to fourth visit. There was no change in feeling of well-being. DISCUSSION: A multidisciplinary clinic is beneficial for the management of cancer cachexia. The greatest benefit was seen over 3 months. Obstacles encountered during the pilot project included late referrals, noncompliance, and difficulty completing questionnaires. The process to develop and implement this clinic may help healthcare professionals improve the management of cancer cachexia.

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Emesis

Abstract PA-02
Assessment of Skin Irritation and Sensitization Potential of a Transdermal Granisetron Patch

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BACKGROUND: Granisetron Transdermal Delivery System (patch) provides extended release of granisetron for up to 7 days for prevention of nausea and vomiting in patients receiving multiday chemotherapy. A phase I, randomized, double-blind study in healthy subjects assessed the local tolerability of the patch. METHODS: A 21-day induction phase (three consecutive applications of the patch every 7 days over 21 days) was followed by a challenge phase (application of the patch to an alternative skin site). In the induction phase, irritation was scored 0–4 according to increasing severity. RESULTS: Of 212 randomized subjects, 201 subjects were analyzed for irritation and 200 for sensitization. During the induction phase, both groups showed similar results on the application site assessment; most subjects in the active and placebo groups experienced either no reaction (Day 8: placebo = 66 [32.8%], active = 91 [45.3%]) or slight erythema (Day 8: placebo = 90 [44.8%], active = 83 [41.3%]) at the application site. During the challenge phase, one of 200 subjects (0.5%) had a positive sensitization reaction, classified by the investigator as erythema with vesicles, delayed marked pruritus, and extension of skin reaction. No subject discontinued treatment due to local, tolerable adverse events. DISCUSSION: The granisetron patch was well tolerated with a low level of irritation and low-sensitization potential. A single

patch application of granisetron may provide a well-tolerated delivery option for control of nausea and vomiting during multiday chemotherapy.

Abstract PA-03

Efficacy of a Transdermal Granisetron Patch for Prevention of Chemotherapy-Induced Nausea and Vomiting According to Patch Adhesiveness, Time of Application, and Daily Control

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Background: As part of a phase III, randomized, double-blind, placebo-controlled study, the efficacy of a novel Granisetron Transdermal Delivery System (GTDS) was assessed based on the time of patch application with respect to chemotherapy dosing and whether the patch became detached. Methods: A total of 641 patients receiving multiday chemotherapy were randomized to GTDS (applied 24–48 hours prior to chemotherapy for 7 days) or oral granisetron (2 mg daily). The time of patch application and degree of adhesion were recorded in the study. Complete control (CC; no vomiting and/or retching, no more than mild nausea, and no rescue medication) of chemotherapy-induced nausea and vomiting from first chemotherapy until 24 hours after the last administration of chemotherapy was assessed according to patch adhesiveness, time of application, and chemotherapy day. Total control (TC; no nausea or vomiting; no withdrawal) was also assessed by day. Results: Safety of the patch during the 24–48 hours of adhesion before chemotherapy was good; the most frequent adverse reaction was constipation (see Table). Discussion: Patch application time between 24–48 hours was not critical for the efficacy of the patch. In addition, the degree of adhesion and time of application of GTDS were not associated with differences in control of nausea and vomiting. Similarly, control was achieved from the first day of chemotherapy and sustained throughout the multiday regimen. Flexibility exists within the use of granisetron patch for healthcare providers or patients to apply the patch between 24–48 hours, without any effect on efficacy, and no significant safety issues.

Complete Control and Total Control

	PATCH		ORAL	
	CC% (n)	TC% (n)	CC% (n)	TC% (n)
Adhesiveness				
≥ 90%	63 (124)		66 (160)	
≥ 75 to < 90%	57 (45)		67 (37)	
≥ 50 to < 75%	61 (11)		55 (6)	
Day 1 between patch application and first chemotherapy dose (h)				
24 to < 36	86 (72/84)		94 (83/88)	
36 to < 48	79 (133/168)		85 (136/160)	
≥ 48	80 (45/56)		89 (58/65)	
Chemotherapy day				
1	82 (250)	78 (239)	89 (277)	85 (267)
2	79 (240)	75 (228)	81 (252)	77 (240)
3	74 (223)	69 (208)	74 (230)	69 (214)
4	78 (218)	73 (204)	79 (222)	72 (204)
5	83 (219)	79 (208)	86 (231)	77 (208)

Abstract PA-04

Efficacy, Safety, and Tolerability of Transdermal Granisetron Patch for Prevention of Multiday Chemotherapy-Induced Nausea and Vomiting: Phase III Trial Results

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Background: Chemotherapy-induced nausea and vomiting (CINV) remains one of the challenges in supportive care for patients receiving chemotherapy. Multiday chemotherapy provides specific advantages for some patients; however, this schedule presents difficulties in control of CINV. Granisetron Transdermal Delivery System (GTDS) provides extended release of granisetron for up to 5 days for prevention of CINV. A phase III, randomized, double-blind, placebo-controlled, noninferiority study compared GTDS with oral granisetron. Methods: In total, 641 patients receiving moderately or highly emetogenic multiday chemotherapy were randomized to GTDS (applied 24–48 hours prior to chemotherapy, by the patient or study staff, for 7 days) or oral granisetron (2 mg daily, administered 1 hour prior to chemotherapy), plus placebo capsule or patch. The primary endpoint was the percentage of patients achieving complete control (CC; no vomiting and/or retching, no more than mild nausea, and no rescue medication) of CINV from first until 24 hours after the last administration of chemotherapy. Results: Noninferiority of GTDS and oral granisetron was demonstrated, with 60.2% of GTDS-treated and 64.8% of oral-treated patients achieving CC (estimate [confidence interval] = –4.89% [–12.9%, 3.1%]). There were no significant differences between treatments in rates of complete response (62.0% GTDS; 68.1% oral) and total control (55.6% GTDS; 59.4% oral). Most patches demonstrated ≥ 75% adhesion (96% active; 99% placebo); only one adverse event (AE) of mild pruritus was reported at the application site. Treatment-emergent AEs were few and comparable between groups, with most events mild or moderate in severity (overall 7.9% GTDS; 5.6% oral). Discussion: GTDS demonstrated noninferiority to oral granisetron in control of CINV associated with multiday chemotherapy and was safe and well tolerated. GTDS provides a valuable treatment delivery option versus repeated oral dosing for prevention of CINV in patients receiving multiday chemotherapy.

Infection

Abstract PA-05

Fever as Cause of Complaint at the Emergency Service in Oncologic Patients

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BACKGROUND: Fever is a frequent cause of complaint for oncologic patients. Although it is not always life-threatening, the patient usually demands emergency attention for this condition. This analysis studied every patient who visited our emergency service for treatment of fever during a 5-month period, examining the diagnosis and clinical decisions made for the patient's care. METHODS: Between October 2007 and March 2008, we attended 251 oncologic patients in our emergency service. This report describes the characteristics, the diagnosis made in the emergency service, and the clinical management of those who were treated for fever. RESULTS: A total of 251 cancer patients were attended in our emergency service; 46 consulted for fever (18.3%). Of those 46, 37 patients were receiving chemotherapy treatment (80.4%). The most common causes of fever were respiratory tract infection (n = 15 [32.6%]); neutropenic fever (n = 12 [26.1%]); fever without clinical focus (n= 8 [17.4%]) and urinary tract infection (n = 5 [10.9%]). Twenty-four patients (52.2%) were admitted to the hospital because of these diagnoses. DISCUSSION: Most of the cancer patients visiting our emergency room because of fever were receiving chemotherapy treatment. Though fever is not always a life-threatening emergency, the onset of an infection is a common complication for oncologic patients. Most patients who consulted our emergency service for fever were finally admitted to hospital.

Myelosuppression

Abstract PA-06

Hematologic Outcomes and Costs of FDA-Approved Fixed Initial Erythropoiesis-Stimulating Agent (ESA) Doses in Cancer Patients With Chemotherapy-Induced Anemia (CIA): Real World Data From an Observational Study

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BACKGROUND: Two fixed initial ESA doses are approved by the US Food and Drug Administration for cancer patients with CIA: 40,000 U of epoetin alfa (EPO; Procrit) and 500 µg of darbepoetin alfa (DARB; Aranesp). To characterize clinical and economic outcomes of patients initiated at fixed doses, data were analyzed from the Dosing and Outcomes Study of Erythropoiesis-Stimulating Therapies (DOSE) Registry, an ongoing prospective observational US study. METHODS: This analysis included cancer patients treated for CIA who received ≥ 2 doses of either ESA between January 2006 and July 2008. Hematologic changes and ESA drug cost (based on cumulative ESA dose and 7/08 WAC: EPO $13.77/1,000 U; DARB $4.722/µg) were assessed. RESULTS: In total, 445 patients (343 EPO, 102 DARB) from 40 sites were included. Age, gender, baseline hemoglobin (Hgb), and treatment duration were similar between groups. Mean cumulative dose (cost) for EPO was 310,362 U ($4,274) and for DARB 1,729 µg ($8,164). Transfusions were required in 12% of EPO patients and 19% of DARB patients (P = 0.10). Mean blood utilization trended lower in the EPO group (U/patient: EPO 0.3; DARB 0.6; P = 0.07). The EPO group had a statistically significantly greater Hgb change at weeks 4 ($P < 0.0001$) and 12 ($P < 0.001$) compared with the DARB group (Table). DISCUSSION: In this analysis of cancer patients with CIA initiated on fixed ESA doses, those receiving EPO resulted in a 48% lower mean ESA cost and better hematologic outcomes compared with those receiving DARB.

Mean HgB Change From Baseline (SD)

	WEEK 4	WEEK 8	WEEK 12	WEEK 16
EPO	0.7 (1.1)	0.7 (1.3)	0.7 (1.3)	0.5 (1.2)
DARB	−0.1 (1.3)	0.0 (2.0)	−0.2 (1.5)	0.2 (1.6)

Abbreviation: HgB = hemoglobin; EPO = epoetin alfa; DARB = darbepoetin alfa

Abstract PA-07

Long-Term Use of Romiplostim in Adult Patients With Chronic Immune Thrombocytopenic Purpura (ITP)

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BACKGROUND: Patients with chronic ITP and platelet counts $< 50 \times 10^9$/L may be at risk for bleeding. Romiplostim is an Fc-peptide fusion protein (peptibody) that increases platelet production via the same mechanism as endogenous thrombopoietin. METHODS: Clinical outcomes were compared between patients receiving romiplostim (n = 83) or placebo (n = 42) in two phase III trials. An ongoing, open-label extension study evaluating long-term (up to 156 weeks) effects of romiplostim on ITP patients (n = 142) was evaluated. The starting weekly dose was 1 µg/kg administered subcutaneously (adjusted to maintain platelet counts of 50–200 × 10^9/L). RE-

sults: In the phase III trials, 83% of romiplostim-treated patients achieved platelet counts of ≥ 50 × 10^9/L for ≥ 4 weeks versus 7% of placebo-treated patients ($P < 0.0001$). Romiplostim reduced the incidence of clinically relevant bleeding events compared with placebo (15% vs 34%; $P = 0.018$). Of romiplostim-treated patients, 87% either reduced or discontinued concomitant ITP medications (vs 38% treated with placebo) and fewer received rescue therapy than placebo (23% vs 60%, respectively). In the extension study, platelet counts ≥ 50 × 10^9/L were maintained for ≥ 10, ≥ 25, and ≥ 52 consecutive weeks in 78%, 54%, and 35% of patients, respectively. The incidence of patient bleeding decreased during long-term treatment from 36% (weeks 1–12) to 12% (weeks 37–48). In total, 84% of patients reduced or discontinued concomitant ITP medications. Rescue medication use decreased from 23% (weeks 1–12) to 14% (weeks 37–48). Most adverse events were mild-to-moderate; the 3 most common in the stage III study were headache, fatigue, epistaxis; and in the extension study were headache, nasopharyngitis, contusion. Discussion: Romiplostim was well tolerated, raised and sustained platelet counts, and reduced the incidence and severity of bleeding events in adult ITP patients.

Nutrition

Abstract PA-08

The Long-Term Follow-up of a Prospective Randomized Controlled Trial of Nutritional Therapy in Head & Neck Cancer Patients Submitted to Radiotherapy

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Background: A randomized controlled trial conducted in 75 head and neck cancer (HNC) patients proved individualized nutritional counseling to be the most effective regimen in reducing radiotherapy (RT) toxicity and improving nutritional intake, status, and quality of life at 3 months after intervention. The present study was to assess survival and late RT toxicity after a long-term follow-up. Methods: Original study groups follow: G1 (n = 25) received individualized nutritional counseling and education (regular foods); G2 (n = 25) received ad lib intake + two polymeric protein supplements; and G3 (n = 25) received ad lib intake. Some data were collected from patients' records at follow-up appointments every 3–6 months; in addition, validated questionnaires to assess symptoms were used at programmed interviews after a median follow-up of 3.8 (range, 2.0–6.3) years (PR). Analyses, per group, and in-between group comparisons were adjusted for cancer stage, age, follow-up time, and survival. Results: Kaplan-Meier method was used to calculate survival curves: in G1, 4 (16%) patients died, in G2 there were 8 (32%) deaths, and 12 (48%) patients died in G3 ($P < 0.05$). Late RT toxicity (permanent xerostomia and/or taste alterations) was higher in G3 and G2 than in G1 ($P < 0.04$); those symptoms were experienced and/or reported by 10 (80%) of G3 patients, by 12 (72%) of G2 patients, and by 10 (52%) of G1 patients: G3 ≈ G2 > G1, $P = 0.05$. Discussion: This study is the first to convey information on long-term follow-up designed to assess the effectiveness of nutrition as adjuvant therapy during RT in patients with HNC. Early individualized nutritional counseling and education seems to improve well-being and possibly prognosis.

Other

Abstract PA-09

Extended Treatment of Venous Thromboembolism in Patients With Cancer: An Analysis of Low-Molecular-Weight Heparin (LMWH) Randomized Clinical Trials

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Background: Patients with cancer often experience disease or treatment-related complications and may need supportive care. Venous thromboembolism (VTE) is one of the most common complications in patients with cancer. Recently, anticoagulant therapies utilizing LMWHs for up to 6 months have shown improved efficacy over vitamin K antagonists (VKAs). However, individual LMWHs have not been compared with each other, and currently there is no standard of practice for the use of LMWH in this setting. Methods: Computerized queries of PubMed, MEDLINE, and the abstract databases for the American Society of Hematology and the American Society of Clinical Oncology were performed to identify randomized clinical trials comparing LMWHs with VKAs in the extended treatment of VTE in patients with cancer. Results: LMWHs are associated with lower rates of recurrent VTE and similar rates of bleeding compared with VKA therapy (Table 1). Dalteparin (Fragmin) is the most extensively studied LMWH in this setting, and it demonstrated a 52% relative risk reduction in recurrent VTE ($P = 0.002$). Dalteparin may also be associated with increased survival, as it demonstrated a 50% reduction in overall mortality in patients without metastatic disease at randomization in a CLOT trial post-hoc analysis. Enoxaparin (Lovenox) is as effective as VKAs and may be safer as prolonged treatment in cancer patients. Tinzaparin (Innohep) reduced the risk of recurrent VTE by half, but the difference was not statistically significant at the end of the 3-month treatment period. Discussion: Long-term LMWHs are more efficacious than VKAs in preventing recurrent VTE in patients with cancer and have a similar safety profile.

LMWH Randomized Clinical Trials

TRIAL	TREATMENT PERIOD	TREATMENT REGIMEN	RECURRENT VTE (LMWH VS VKA)	BLEEDING (LMWH VS VKA)
CANTHANOX* (n = 147)	3 mo	Enoxaparin 1.5 mg/kg once daily vs VKA	2/71 (2.8%) vs 3/75 (4%) (*P* = 0.09) RR = 0.7	5/71 (7%) vs 12/75 (16%)
ONCENOX* (n = 101)	3 mo	Enoxaparin 1.5 mg/kg once daily vs enoxaparin 1.0 mg/kg twice daily vs VKA	No differences in recurrent VTE, major bleeding, or death	
CLOT (n = 676)	6 mo	Dalteparin 200 IU/kg SC daily for 1 month, then 150 IU/kg SC daily for 5 months vs VKA	27/336 (8%) vs 53/336 (15.7%) RR = 0.48	47/336 (14%) vs 63/336 (18.8%)
LITE (n = 200)	3 mo	Tinzaparin 175 IU/kg SC daily vs VKA	3-mo analysis: 6/100 (6%) vs 10/100 (10%) 12-mo analysis: 16/100 (16%) vs 7/100 (7%) *P* = 0.044 RR = 0.44	27/100 (27%) vs 24/100 (24%)

*Trial discontinued due to low enrollment.

Abbreviation: LMWH = low-molecular-weight heparin; VTE = venous thromboembolism; VKA = vitamin K antagonists; SC = subcutaneous; RR = relative risk

Pain

Abstract PA-10

Reducing Barriers to Pain and Fatigue Management

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BACKGROUND: Pain and fatigue impact all dimensions of quality of life (QOL), including physical, psychologic, social, and spiritual well-being. The purpose of this prospective longitudinal study funded by the National Cancer Institute is to test an innovative model of reducing barriers to managing pain and fatigue in cancer patients. The study intervention is based on evidence-based guidelines from the National Comprehensive Cancer Network. Results are provided from the second phase of this three-phase study. METHODS: Patient education packets were created for managing symptoms (ie, energy conservation/exercise, sleep/wake patterns, nutrition, constipation, and the emotional/social impact of pain and fatigue). The education was provided after baseline assessment and follow-up at 1 and 3 months. RESULTS: The Usual Care group (phase I, n = 83) was compared with the intervention group (phase II, n = 100). Analysis was conducted using a 2 × 3 repeated measures analysis of variance (ANOVA) comparing Usual Care versus Intensive Intervention. There was a significant main effect for change over time (regardless of group) in fatigue, psychologic QOL, treatment distress, anxiety, depression, beliefs about pain relief and the danger of addiction, and beliefs about fatigue relief. Except for treatment distress, the QOL items demonstrated significant improvement between baseline and 3 months. QOL in relation to treatment distress actually decreased significantly at 1 and 3 months when compared with baseline. The beliefs representing barriers to pain and fatigue control were reduced between baseline and 3 months. DISCUSSION: This patient education intervention was effective and well received by clinic physicians and nurses. Phase III will now focus on integration of this intervention into usual care.

Abstract PA-11

Palliative Radiotherapy for Painful Metastases to Bone in the Very Elderly

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BACKGROUND: Radiotherapy frequently is effective in relieving bone pain from metastatic cancer. For the very elderly patient, multiple daily radiotherapy treatments can be burdensome to the patient and family. This report evaluates short-course palliative radiotherapy for metastases to bone in the very elderly. METHODS: From 1988 to 2004, 55 patients, all older than age 80, were treated with 101 radiotherapy courses (range, 1–6) for metastases to bone. All had pain and radiographic evidence of bone involvement. The most common primary cancers were carcinomas of the prostate (n = 24), breasts (n = 8), and lungs (n = 6). Portions of the spine and pelvis-hip region were the most commonly irradiated sites. Most courses (n = 75) consisted of only 1–5 daily treatments. RESULTS: Survival at 6 months from completion of the first or only course of radiotherapy was 51.9%, with only 28.9% alive at 12 months. For patients with primary breast, prostate, and other cancers, the median survival was 14, 10, and 3.5 months, respectively. Most patients derived significant pain relief regardless of the fractionation regimen or the number of treatments administered. Seven patients had a same-bone site reirradiated for persistent or recurrent pain. DISCUSSION: Because of the poor survival of very elderly patients with metastases to the bone and the equivalent benefit of shorter versus prolonged courses of radiotherapy, the author recommends administering only 1–5 treatments for metastases to the bone.

Abstract PA-12

Assessment of Analgesia and Adverse Effects of Controlled Release Tramadol and Dihydrocodeine in Patients With Cancer Pain—Based on a Modified ESAS

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BACKGROUND: This study examined the efficacy of tramadol and dihydrocodeine in patients with cancer pain. METHODS: This open, prospective, randomized crossover study included 30 patients with nociceptive (visceral or somatic) cancer pain treated previously

with non-opioids. Patients received either tramadol (n = 15) or dihydrocodeine (DHC; n = 15) in controlled-release tablets for 7 days; the drugs were then changed and administered for the next 7 days. Analgesia was assessed by visual analogue (VAS) scale, and adverse effects by a modified Edmonton Symptom Assessment System (ESAS), with two additional scales for constipation and vomiting. Starting doses were 100 mg of tramadol and 60 mg of DHC 60, both given twice daily, titrated to satisfactory analgesia. Results: In both groups, better analgesia was seen with DHC. After study completion, 19 patients preferred DHC, 4 preferred tramadol, and 7 assessed both drugs equally effective. Patients in the DHC group reported less dyspnea in the first 7 days and in the second week reported more constipation and a trend toward more drowsiness; patients in this group were more active in the first week and had a better sensation of well-being during both weeks. Patients treated with tramadol experienced more nausea during both weeks. No differences in appetite and vomiting were observed; in the first week, patients treated with DHC were less anxious and depressed. Serious adverse effects (respiratory depression, allergy for drugs) were not observed. Discussion: Tramadol and DHC in controlled-release tablets are effective analgesics in nociceptive cancer pain. No serious adverse effects were observed, although more constipation in the DHC group suggests the need for the prophylactic use of laxatives, whereas more nausea in the tramadol group is an indication for prophylactic antiemetics. Equianalgesic single doses of tramadol to DHC at a 10:6 ratio rendered satisfactory analgesia.

Abstract PA-13

High Outpatient Pain Scores Predict for Hospitalization in a Comprehensive Cancer Center

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Background: This study was designed to determine whether high outpatient encounter pain intensity scores (PIS) identify patients at risk for admission. Methods: Numerical PIS (0–10) are obtained with each outpatient visit at the Johns Hopkins Cancer Center and stored in a database. PIS from all outpatient medical and radiation oncology encounters from 2004 to 2006 were merged with an inpatient database to screen for admissions occurring within 30 days of the outpatient encounter. Descriptive statistics were used to summarize age, gender, diagnosis, and admissions. PIS were categorized as 0–3 (mild), 4–6 (moderate), and 7–10 (severe). Odds ratios (OR) for hospital admission were calculated using logistic regression analyses. Results: Of 119,069 encounters, 116,713 (98%) were evaluable. In total, 5,089 (4.5%) encounters had PIS of 7–10, and 29% of them had hospital admissions within 30 days. Encounters with PIS of 7–10 and 4–6 were 247% and 77% more likely to result in hospital admission within 30 days compared with encounters with PIS < 4 ($P < 0.0001$). Hospital admission rates following encounters with PIS of 7–10 were highest in patients with melanoma (58%), sarcoma (42%), female genital cancers (39%), and upper aerodigestive (36%) cancers. Patients with PIS of 7–10 who were < 46 years old were more likely to be admitted to the hospital than patients > 70 years (OR, 1.38). Discussion: Outpatients with cancer and high PIS are at high risk for hospital admission within 30 days. These patients should be provided early supportive care interventions aimed at improving quality of life and reducing hospitalizations.

Palliative Medicine

Abstract PA-14

Development of an Interdisciplinary Supportive Care Plan for Patients With Lung Cancer

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Background: Lung cancer impacts all dimensions of physical, psychologic, social, and spiritual well-being. Phase I of this two-phase study of QOL and symptoms in patients with lung cancer determined the usual care in a cohort of lung cancer patients treated at a comprehensive cancer center. Phase II evaluated patients currently in treatment regarding their QOL concerns and needed services and pilot tested a palliative care intervention. Methods: In phase I, 100 patients were randomly selected from 125 lung cancer patients seen over a 12-month period. An audit tool reflecting aspects of quality care as described by the National Comprehensive Cancer Network was developed and tested to establish reliability. Care was audited for a 6-month period to capture all resources used. In phase II, 10 patients completed 4 quantitative tools and a tape-recorded interview. Patient data were summarized into a care plan reviewed in the interdisciplinary case conference. Patient follow-up occurred 1 and 3 months post case conference. Results: Phase I data revealed that 32% received no supportive care services. Uncontrolled symptoms were the main reason for outpatient visits and for 38% of hospital readmissions. Phase II data revealed symptom-specific scores were moderate (20.6) as were overall scores for QOL using the Functional Assessment of Cancer Therapy–Lung (87.8). Emotional well-being scores were the lowest (18.4), followed by functional (21.1), social/family (23.8), and physical (24.5). Supportive care services recommended included nutrition, psychology/psychiatry, social work, rehabilitation, and chaplaincy. Discussion: QOL/symptom concerns are often neglected in usual care in lung cancer. An interdisciplinary palliative care intervention can prospectively meet these needs.

Abstract PA-15

Percutaneous Anterior Column Stabilization in Metastatic Spine Lesions: Value of Plasma-Mediated Radiofrequency Ablation and Cement Augmentation

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Background: Annually, over 61,000 cancer patients suffer from spinal metastases, which often cause painful vertebral compression fractures (VCFs), reducing their quality of life. Traditional treatments attempt anterior stabilization through restoring integrity to the anterior two thirds of the vertebral body, but these attempts are often invasive, resulting in poor outcomes. A new minimally invasive option uses a plasma-mediated device to debulk the tumor prior to cement augmentation. This study examined the bone cement deposition patterns in vertebral bodies treated via this combined approach to determine whether it provides acceptable pain relief secondary to anterior stabilization for this patient population. Methods: Patients (n = 30) with metastatic spine lesions stemming from a primary cancer were treated. A plasma-mediated radiofrequency-based device debulked the lesion, and then bone cement was injected into the cavity. Computed tomography scans were collected immediately post procedure to determine bone cement deposition patterns. Patients reported pain status before surgery and 2–4 weeks post procedure. Results: In 28/34 levels (82.3%) treated, more than 75% of the bone cement was deposited in the anterior two thirds of the vertebral body. In nine cases, the cement was deposited in the anterior column. In 20 (58%) of the treated levels, traces of cement were detected outside the vertebral body: 14 cortical, 5 venous, 1 epidural. Cement extravasation was clinically inconsequential in all cases. In total, 25 patients (83%) reported pain relief following the procedure. Discussion: Plasma-mediated radiofrequency ablation provides better control over cement deposition and increases the likelihood of success in stabilizing the anterior two thirds of the vertebral body. The resultant pattern of cement deposition adds stability and grants pain relief.

Abstract PA-16

Effectiveness of Palliative Care Integration in a Community Oncology Center: A Pilot Study

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Background: Despite the widespread recognition of the need for new models of care to better serve patients with advanced cancer, little evidence exists documenting the effectiveness of these models. Little is known about how palliative care (PC) services in a community cancer center can affect healthcare resource utilization in patients receiving cancer-focused, life-prolonging care. The purpose of this pilot study was to investigate the integration of an on-site PC advanced practice nurse (APRN) in the community oncology setting and the effect of PC services on patients with advanced cancer compared with usual care. Methods: This study used a descriptive, pre/post design with 101 adult patients with advanced cancer (stage III/IV). Accrual occurred for 5 months in the usual care period (arm A; n = 52), followed by 5 months of accrual after implementation of the PC APRN (arm B; n = 49). Data were collected at enrollment (T1) and 4 months post enrollment (T2). Data were analyzed using chi-square and logistic regression analyses. Results: Controlling for health-related QOL variables, eight covariates were entered into two logistic regression models, with hospitalization and mortality as outcome measures. Those patients who received PC had a significantly lower mortality rate at 4 months (OR = 15.4; $P < 0.02$) and were five times less likely to be hospitalized (OR = 0.20; $P < 0.01$). Discussion: Contrary to popular belief, PC services can be effectively provided to patients as they receive chemotherapy treatment and are not associated with increased mortality. Access to a PC APRN integrated into the community oncology setting may be associated with measurable benefits.

Abstract PA-17

Methylnaltrexone Treatment of Opioid-Induced Constipation in Patients With CNS Metastases

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Background: Methylnaltrexone (Relistor), a μ-opioid receptor antagonist with limited central nervous system (CNS) access, rapidly induces laxation for treatment of opioid-induced constipation (OIC) in patients with advanced illnesses. Because patients with CNS metastases may have a compromised blood-brain barrier, we examined central opioid withdrawal symptoms, pain intensity, and adverse events (AEs) in these patients with OIC receiving subcutaneous methylnaltrexone. Methods: In this post-hoc analysis of data collected prospectively in two phase III placebo-controlled studies, patients with advanced illness and a cancer diagnosis were stratified by baseline presence of CNS metastases. Central opioid withdrawal symptoms were measured using a modified Himmelsbach Withdrawal score. Results were evaluated at day 1. Results: In total, 43 of 222 (19.4%) cancer patients (19 placebo, 24 methylnaltrexone) had CNS metastases in these two studies. Total Himmelsbach Withdrawal scores on day 1 showed essentially no change with methylnaltrexone treatment in patients with CNS metastases.

Likewise, there was no statistically significant change in current or worst pain score from baseline at day 1 by CNS metastasis status (present or absent) or treatment (methylnaltrexone versus placebo). The relative incidences of neurologic AEs (dizziness, lethargy, somnolence, depressed level of consciousness, and seizure) observed with methylnaltrexone versus placebo were similar between patients with and without CNS metastases. Discussion: Studies of methylnaltrexone for treatment of OIC in patients with advanced illness showed similar overall safety profiles and no evidence of decreased analgesia or central opioid withdrawal in cancer patients with or without CNS metastases, suggesting that methylnaltrexone has no clinically significant central effects in patients with CNS metastases.

Psycho-oncology

Abstract PA-18

Broaching the Subject of Grief in a Community-Based Cancer Center: What Have We Learned After Three Years?

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Background: The palliative care team at a community cancer center identified a need for bereavement services and started a program in 2005. In 3 years, the number of families in this program tripled from 64 to 204. Methods: Earlier procedures for follow-up with survivors were found to be limited. We created a program of largely by-mail contacts over 13 months. Letters and other materials were carefully crafted to encourage different ways of expressing grief. Flyers at 6 months identified signs of recovery and information about when to contact a professional. Families also could attend a monthly support group or receive individual therapy. Results: The importance of identifying an individual (bereavement coordinator) to initiate timely mailings and to facilitate referrals is key. We found survivors to be nonreceptive to completing satisfaction surveys at any point. Families attending the support group were less inclined to want refreshments but grateful for parking and a meeting location away from the cancer center. Many families said the receipt of periodic correspondence was comforting, especially several months after the death, when things returned to a so-called normal state. This finding was especially rewarding to us because the number of families participating in individual or group therapy was small. Discussion: Successful bereavement programs should offer a variety of ways for families to explore loss and understand the grieving process. Program content should offer written materials as well as the opportunity to meet with others. The number of families actually needing additional strategies to transition loss likely will be small.

Abstract PA-19

An Observational Study of Disparities in Outpatient Antidepressant Prescribing Patterns and Determinants of Resource Utilization at a Cancer Center

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Background: Multiple agents are available for the treatment of depression in cancer patients. This study was designed to assess the usage prevalence, prescribing patterns, exposure determinants, and resource utilization among classes of antidepressants at a comprehensive cancer center in the years 2001 and 2006. Methods: Demographic characteristics, diagnosis, comorbidities, prescribing physician and service, type and number of antidepressant prescriptions, and resource utilization data were collected. Pearson's chi-square and unpaired *t*-tests analyzed the differences between demographic characteristics, prescription patterns, and resource utilization. Mantel-Haenszel stratified analysis was used to evaluate the effect of sex and ethnicity on usage patterns. Logistic regression was conducted to identify predictors of antidepressant type prescribed and amount and type of resource used. P values < 0.05 were considered significant. Results: Significant differences in sex and ethnicity were found in the prescribing and usage patterns of antidepressants, with women seeing a psychiatrist more often than men ($P = 0.001$) and Caucasians receiving more selective serotonin reuptake inhibitors (SSRIs) than other ethnic groups ($P = 0.002$). In terms of resource utilization, males had significantly more hospital admissions ($P < 0.0001$) and emergency room visits ($P = 0.004$), whereas non-Caucasian ethnic groups had more emergency room visits ($P < 0.0001$) and clinic visits ($P = 0.001$). Discussion: This study identifies areas where disparities might exist in the management and treatment of depression in patients with cancer. Further investigation regarding the screening, evaluation, and treatment for depression is necessary to confirm disparities and evaluate possible causes.

Quality of Life

Abstract PA-20

Quality of Life (QOL) in Patients With Advanced Pancreatic Cancer (APC) Receiving Chemotherapy: Results From a Prospective Multicenter Phase II Trial

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Background: Pancreatic cancer is rapidly fatal, with a median survival of only 6 months. QOL was analyzed prospectively in a

phase II study of gemcitabine (Gemzar), capecitabine (Xeloda), and bevacizumab (Avastin) in APC patients. METHODS: In total, 50 patients with APC received gemcitabine (1,000 mg/m^2) on days 1 and 8, capecitabine (650 mg/m^2) orally twice daily from days 1–14, and bevacizumab (15 mg/kg) on day 1 every 3 weeks. Endpoints were progression-free survival (PFS), overall survival (OS), and QOL. QOL assessment prior to each cycle was done using the EORTC PAN-26 QOL questionnaire. An exact 95% confidence interval (CI; Clopper-Pearson method) was used to assess the rate of improved QOL (defined as > 5% decrease in two consecutive scores compared with baseline). RESULTS: Patient characteristics follow: 4/46 were stage III/IV; 28 were male, 22 were female; and the median age was 64 years (range, 38–83 years). QOL results saw improvements in 28 patients (56%), no improvement in 12 patients (24%); and were unevaluable in 10 patients (20%). Median PFS was 5.8 months, and OS was 9.8 months. QOL improvement rate was 28/40 = 0.7 (95% CI: 0.53–0.83) in evaluable patients (QOL improvement with gemcitabine alone is 0.2). Using the rate of QOL improvement, no significant difference was seen in patients with OS > 6 months compared with OS < 6 months ($P = 0.1680$). QOL scores at visits 2 and 3 correlated strongly with 6-month survival. (Visit 2: $P = 0.0092$; Visit 3: $P = 0.0081$). DISCUSSION: In this population, the use of gemcitabine, capecitabine, and bevacizumab is associated with improved PFS, OS, and QOL. Baseline score and change in QOL scores were not predictive of survival > 6 months. However, post-treatment scores at 3 and 6 weeks from the start of therapy were predictive of survival > 6 months, suggesting the potential predictive value of this tool for use in future studies.

Abstract PA-21

Weight Loss During Treatment of Head and Neck Cancer as an Independent Predictor of Quality of Life and Symptom Burden

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BACKGROUND: Head and neck cancer patients are particularly susceptible to weight loss during treatment due to both treatment side effects and impaired caloric intake. It is not known whether weight loss during active treatment is a predictor of quality of life (QOL) and symptom distress independent of other clinical variables. METHODS: In total, 68 patients with newly diagnosed head and neck cancer undergoing initial treatment were enrolled in this study. The Functional Assessment of Cancer Therapy–Head and Neck (FACT–H&N) and Memorial Symptom Assessment Scale (MSAS) were used to measure QOL and symptom distress, respectively, before, during, and after initial treatment. RESULTS: Of 68 patients, 7 lost no weight or gained weight, 21 lost 1%–5%, 25 lost 6%–10%, and 15 lost more than 10% of their pretreatment weight. There was no difference in QOL or symptom distress before or after treatment between these four groups. However, based upon mid-treatment measures, weight loss during treatment predicted lower QOL ($P = 0.017$) and higher symptom distress ($P = 0.022$). Multiple regression analysis showed that weight loss predicted lower QOL ($P = 0.029$) and higher symptom distress ($P = 0.015$) independent of age, gender, tumor stage, and chemotherapy use. DISCUSSION: Weight loss is a simple and independent measure predictive of patients with lower QOL and higher symptom distress during head and neck cancer treatment. Studies to evaluate whether interventions that maintain weight during treatment effectively improve QOL and lower symptom distress are warranted.

Abstract PA-22

PHY906 and Incidence of Chemotherapy-Induced Diarrhea (CID) in Patients With Gastrointestinal (GI) Malignancies

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BACKGROUND: According to Hoff et al (*J Clin Oncol 2001;18:2282–2292*), 15.4% of patients treated with capecitabine (Xeloda) alone had grade 3/4 diarrhea. PHY906 is formulated based on an ancient Chinese botanical composed of *Scutellaria, Glycyrrhiza, Ziziphus, and Paeonia*. Preclinical studies showed synergistic activity of PHY906 with chemotherapeutics and reduction of chemotherapy-induced GI toxicities, especially CID. METHODS: We conducted a phase I safety and efficacy trial of capecitabine + PHY906 in patients with GI malignancy who failed to respond to standard therapy. Patients received PHY906 (800 mg twice daily from days 1–4) with escalating doses of capecitabine (1,000 mg/m^2→1,250 mg/m^2→1,500 mg/m^2→1,750 mg/m^2 twice daily from days 1–7) followed by 7 days of rest, until maximum tolerated dose and toxicity were assessed per National Cancer Institute-Common Terminology Criteria for Adverse Events v3.0. We prospectively evaluated for diarrhea and compared our data with historical controls. RESULTS: In total, 24 patients (19 M/5 F; median age = 64 years) received 111 cycles (median = 5.5) of PHY906 in four capecitabine-7/7 escalation cohorts: 1,000 mg/m^2 (n = 6), 1,250 mg/m^2 (n = 3), 1,500 mg/m^2 (n = 7), and 1,750 mg/m^2 (n = 8). One dose-limiting toxicity (grade 4 AST/ALT) was observed in one patient at 1,000 mg/m^2 dose. Grade 3/4 diarrhea was observed only in two (3%) patients, at the 1,750 mg/m^2 dose level. One patient who received 9 cycles at the 1,500 mg/m^2 dose level was diarrhea-free until a protocol violation; he continued on single-agent capecitabine and developed diarrhea. DISCUSSION: PHY906 reduced CID by 80.5% in patients treated with capecitabine compared with historic controls. As an underlying mechanism of CID may include cytokine activation, we intend to explore the effects of PHY906 on the cytokine levels in a phase II trial where quality of life measures will be an endpoint.

Abstract PA-23

A Multivariate Analysis of the Effect of Cancer Symptoms on Quality of Life in Prostate Cancer

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Background: Patients undergoing treatment for advanced cancer experience symptoms that occur with varying frequency, intensity, and impact. We conducted a multivariate analysis to investigate the impact of cancer symptoms on quality of life (QOL) in prostate cancer. Methods: A consecutive series of 147 prostate cancer patients treated at Cancer Treatment Centers of America. Cancer symptoms were assessed using the symptom subscales of EORTC QLQ–C30. Scores range from 0–100; lower scores indicated better symptoms. QOL was assessed using Ferrans and Powers Quality of Life Index (QLI). QLI measures overall QOL and QOL in four subscales: health/physical, social/economic, psychologic/spiritual, and family. Scores range from 0–30; higher scores indicate better QOL. Results: In total, 104 were newly diagnosed, whereas 43 had failed prior treatment. The mean age at presentation was 65.2 years. The majority of patients had stage II (104) disease at diagnosis. Every 10-unit increase in fatigue ($P = 0.001$), nausea ($P = 0.001$), pain ($P = 0.03$), insomnia ($P = 0.001$), and appetite loss ($P = 0.04$) was associated with 0.95, 1.4, 0.36, 0.62, and 0.38 unit decline in QLI health/physical subscale after controlling for age, treatment history, tumor stage, and other symptoms. Insomnia was an independent predictor of psychologic ($P = 0.01$) and family ($P = 0.01$) subscales. Every 10-unit increase in fatigue ($P = 0.01$) and insomnia ($P = 0.001$) was associated with a 0.52 and 0.46 unit decline in overall QOL. Discussion: Fatigue, nausea, pain, appetite loss, and insomnia are independent predictors of QOL after controlling for each other, age, treatment history, and tumor stage. Recognition and timely treatment of symptom clusters could result in improved QOL in prostate cancer.

Abstract PA-24

A Prospective Randomized Controlled Trial of Nutritional Therapy in Colorectal Cancer Patients Submitted to Radiotherapy: The Long-Term Follow-Up

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Background: In our published randomized controlled trial conducted in 111 colorectal cancer (CRC) patients, G1 (n = 37) received individualized nutritional counseling and education (regular foods); G2 (n = 37), ad lib + polymeric protein supplements and G3 (n = 37), ad lib food intake. Early individualized nutritional counseling during radiotherapy (RT) was shown to be the most effective regimen in reducing RT toxicity, improving nutritional intake, status, and quality of life (QOL); efficacy persisted at 3 months after the intervention. The aim in this study was to evaluate the long-term follow-up of the clinical trial with regard to survival, late RT-induced toxicity, QOL, and disease outcome. Methods: Data were collected from patients' records. Analyses, per group, in-between group comparisons (adjusted for cancer stage and survival), were performed after a median follow-up of 4.1 (2.0–6.3) years. Results: All patients complied with follow-up every 3–6 months. All were alive in G1, whereas there were 4 (11%) deaths in G2 and 7 (19%) deaths in G3 ($P < 0.05$). Likewise, late RT-induced toxicity (permanent flatulence, abdominal distension, diarrhea) was higher in G3 and G2 when compared with G1 ($P < 0.001$); these symptoms were experienced and/or reported by 27 (90%) of G3 patients, by 29 (88%) of G2 patients, and by just 2 (5%) patients in G1: G3≈G2>G1 ($P = 0.002$). with regard to QOL, scores were the highest in G1, were similar to those reported at the 3-month follow-up, and were associated with adequate intake/nutritional status ($P < 0.05$). In G2 and G3, all QOL scores decreased by the 3-month follow-up ($P < 0.05$); G1>G2≈G3 ($P < 0.002$), and lower QOL scores in G2 and G3 were associated with deterioration of nutritional intake and status ($P < 0.01$). Discussion: This study conveys novel information on the likely effectiveness of nutrition in improving CRC long term well-being, QOL, and possibly prognosis. We have shown that early individualized nutritional counseling and education during RT treatment are valuable assets.

Rehabilitation

Abstract PA-25

Adherence to a Physical Activity Program for Women Receiving Chemotherapy for Breast Cancer

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Background: Patients' ability to adhere to home-based physical activity (PA) interventions during chemotherapy is unknown. The purpose of this study was to evaluate adherence to a prescribed PA program during chemotherapy. Methods: A longitudinal study was conducted with patients aged 40–55 during breast cancer chemotherapy. Participants were randomized to join a home-based PA program comparing the impact of PA versus bisphosphonates on bone mineral density. PA participants were advised to walk 10,000 steps/day and received PA consultation and ongoing motivational interviewing. Pedometers were used to track steps/day. Adherence to the 10,000-step protocol was estimated with total steps/participant and mean steps/day over the first 6 study weeks. Multilevel modeling was used to evaluate PA program adherence. Results: In total, 36 women were enrolled in the PA intervention; 29 provided 6-week data. Mean total

steps/participant for the 6 weeks was 280,571 (SD = 111,992), or 67% of prescribed steps. Excluding days without steps recorded, mean steps/day for this period was 7,363 (SD = 2,421), yielding a 74% adherence rate. Mixed model comparison was conducted to determine the steps/day within chemotherapy cycles. There was a significant linear increase in the step counts with the number of days after chemotherapy ($P < 0.0001$). Hours spent sleeping/reclining were inversely related to steps/day ($P = 0.0001$). Physical, psychologic, and treatment variables did not predict steps/day on multivariate analysis. Discussion: Although breast cancer patients had relatively good adherence to the PA program, chemotherapy treatment affected participation. Chemotherapy caused an immediate decline in step counts on treatment days and gradual linear improvement until the next chemotherapy treatment.

Skeletal Complications

Abstract PA-26

Toremifene Improved Multiple Side Effects of Androgen-Deprivation Therapy (ADT) and Slowed PSA Progression in Men in Phase III Clinical Trial

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Background: Men with advanced prostate cancer can expect to be treated with ADT for 10 or more years, subjecting them to serious side effects including life-threatening fractures. We conducted a randomized placebo-controlled phase III trial to examine the ability of toremifene (Fareston) to prevent fractures and to treat other estrogen-related side effects of ADT in men with advanced prostate cancer. Methods: In total, 1,389 men with advanced prostate cancer were randomized to receive either 80 mg of toremifene orally or placebo for up to 24 months. The primary endpoint was new vertebral fractures, and secondary endpoints included bone mineral density (BMD), lipid profile, hot flashes, and gynecomastia. A post-hoc safety analysis of prostate-specific antigen (PSA) progression was also conducted. Results: Toremifene reduced vertebral fractures by 54% compared with placebo ($P = 0.032$). There was also a 56% reduction in first of either a nontraumatic fracture or > 7% bone loss (placebo 23.8% vs 10.5% toremifene; $P < 0.0001$). Toremifene had statistically significant improvements in lipid profile, BMD, gynecomastia, and hot flashes. Importantly, there was a statistically significant improvement in PSA progression in the toremifene treated group compared with placebo ($P = 0.021$) among patients with a detectable baseline PSA. There were more thromboembolic events in the treated group compared with placebo (2.4% vs 1%), but all non-fatal. Discussion: In this randomized placebo-controlled trial, toremifene demonstrated the ability to prevent fractures and other key estrogen-related side effects in men on ADT.

Skin Toxicity

Abstract PA-27

Incidence and Risk of Skin Toxicity With Erlotinib: A Systematic Review and Meta-Analysis

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Background: Erlotinib (Tarceva), an inhibitor of epidermal growth factor receptor tyrosine kinase, has been used in the treatment of solid tumors, including non-small cell lung cancer (NSCLC). The major side effect of this agent is skin rash. This study aims to quantify the risk of skin toxicity through a meta-analysis of published clinical trials. Methods: Data were collected through Medline (1966 to March 2008) and abstracts presented at the American Society of Clinical Oncology Conferences from 2004 through 2008. Eligible studies were phase II and III clinical trials of cancer patients using erlotinib at 150 mg daily as single agent or in combination with chemotherapy. Incidence, relative risk (RR), and 95% confidence intervals (CI) were calculated using random-effects or fixed-effects models based on the heterogeneity of included studies. Results: A total of 12,709 patients with NSCLC and other solid tumors from 36 trials were included for analysis. The overall incidence of all-grade and high-grade (grade 3/4) skin rash associated with erlotinib was 73.5% (95% CI: 70.2%–76.7%) and 10.5% (95% CI: 9.2%–12.1%) respectively. There is a significantly increased risk of skin toxicity with erlotinib in comparison with controls (all-grade: RR 3.07, 95% CI: 2.02–4.50, $P < 0.001$). Interestingly, combination with chemotherapeutic or biologic agents may decrease the risk of skin rash (RR 0.79, $P < 0.001$). Discussion: There is a significantly increased risk of all-grade and high-grade skin toxicity among patients receiving erlotinib. Combination with chemotherapeutic or biologic agents may decrease the risk of skin rashes. Further studies are recommended to investigate the mechanism of skin toxicity.