and for whom Hb values had been collected at various times between study days -30 and 400. We then retrospectively analyzed estimated Hb values for baseline and Weeks 1, 4, 8, and 10 (Days 0, 7, 28, 56, and 70) for 1,285 of the 1,646 patients who had recorded Hb values for each week from baseline through at least Week 10.

**Results:** As shown below, mean Hb levels for the 1,285 patients increased from 9.7 g/dL at baseline to 11.5 g/dL by Week 10 in the epoetin alfa treatment group, and from 9.7 g/dL to 9.9 g/dL at the same time point in the placebo group. Comparison of the mean changes in Hb values from baseline to each subsequent study week showed significantly ($P<.001$) greater increases in Hb level for the epoetin alfa group than for the placebo group at each evaluation, beginning at Week 1. In the epoetin alfa group, the Hb response was rapid, with increases of 1.0 g/dL by Week 4 and 1.7 g/dL by Week 8.

| Week | Mean Hb Level (g/dL) | | Mean Change in Hb Level (g/dL) | |
|---|---|---|---|---|
| | Epoetin alfa (n = 771) | Placebo (n = 514) | Epoetin alfa (n = 771) | Placebo (n = 514) |
| Baseline | 9.7 | 9.7 | – | – |
| 1 | 9.8 | 9.5 | 0.1* | -0.1 |
| 4 | 10.7 | 9.7 | 1.0* | 0.0 |
| 8 | 11.4 | 9.9 | 1.7* | 0.2 |
| 10 | 11.5 | 9.9 | 1.8* | 0.3 |

*$P<.001$; epoetin alfa vs placebo, 2-sample *t* test

**Conclusion:** Results of this meta-analysis confirm those of earlier randomized (Littlewood 2001) and non-randomized studies, indicating that the administration of epoetin alfa to anemic cancer patients undergoing chemotherapy results in a rapid increase in Hb level. These findings are clinically relevant, as maintaining Hb levels around 12 g/dL or higher during chemotherapy can prevent the deterioration in QOL associated with anemia and its sequelae, particularly fatigue.

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## The oral NK1 antagonist aprepitant for the prevention of chemotherapy induced nausea and vomiting: pooled data from 2 randomized, double-blind, placebo controlled trials

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**Background:** In each of 2 randomized, double-blind Phase III studies of identical design, the novel NK antagonist aprepitant was shown to enhance the efficacy of standard antiemetic therapy (a 5-HT antagonist plus a corticosteroid) for prevention of cisplatin induced nausea and vomiting. Data were pooled from the 2 studies to obtain more precise estimates of treatment effects with aprepitant.

**Methods**: Approximately 1040 patients receiving their first cisplatin (* 70mg/m$^2$) took either standard therapy (ondansetron [O] 32 mg i.v. and dexamethasone [D] 20 mg p.o. on day 1; D 8 mg twice daily on days 2-4) or an aprepitant (A) regimen (A 125 mg p.o. plus O 32 mg and D 12 mg on day 1, A 80 mg and D 8 mg once daily on days 2-3, and D 8 mg on day 4). Rescue therapy was permitted for established nausea or vomiting. Patients rated nausea daily on a 100-mm visual analogue scale (VAS). The primary endpoint was complete response (no emesis and no rescue therapy) for the combined analyses of efficacy, which were prespecified for the acute phase (0-24 h post cisplatin) and post hoc for the delayed phase (24-120 h) and overall study period (0-120 h). A post hoc analysis of nausea scores was also performed using endpoints of no nausea (VAS peak score <5mm) and no significant nausea (VAS peak score <25mm) for the overall 5-day study period. Data were captured in patient diaries and analyzed by a modified intent-to-treat approach. Treatment comparisons were made using logistic regression. Tolerability was assessed by adverse events and physical/laboratory tests.

**Results**: Patient baseline characteristics were similar between groups. The percentages of patients with complete response in the acute phase (0-24 h) were significantly higher with the aprepitant regimen versus standard therapy (86.0% v 73.2%; $p<0.001$). Similar superiority was observed for the aprepitant regimen in the delayed phase (25-120 h) (71.5% v 51.2%; $p<0.001$) and for the overall 5-day study period (67.7% vs. 47.8%; $p<0.001$). Likewise, compared with patients taking standard therapy, significantly higher percentages of patients on the aprepitant regimen had no nausea (48.2% v 41.5%; $p<0.05$) and no significant nausea (72.1% v 64.9%; $p<0.05$) in the overall study period. Similar incidences of adverse events were reported between treatment groups, and the aprepitant regimen was generally well tolerated. Compared with standard therapy alone, addition of aprepitant to standard therapy provided consistently superior and generally well tolerated antiemetic protection throughout the acute and delayed phases, as shown by data pooled from 2 large Phase III trials in patients receiving highly emetogenic chemotherapy.

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## Prevention and management of radiation skin reactions: a randomised controlled trial of skin care approaches in patients with breast, head and neck and anorectal cancer

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**Background:**Although radiation-induced skin reactions are common, there is little evidence upon which to base their management. Previous, small-scale, studies had suggested that sucralfate cream and hydrogels might be effective in the management of skin reactions during and after radiotherapy. We therefore performed a randomised trial on 357 patients to investigate these claims.

**Methods:**Patients were randomised to apply aqueous cream, sucralfate cream or no cream from the start of radiotherapy, and were supplied with either dry dressings or hydrogel (Intrasite®) dressings (according to their randomised group) for use in the event of moist desquamation. All patients were encouraged to wash with mild soap and water and were given consistent skin care instructions. Skin reactions were assessed weekly using a modified RTOG score and erythema was measured objectively using reflectance spectrophotometry. Patients completed a daily diary card assessing pain, itching, burning, sleep disturbance and skin appearance. Weekly quality of life scores were obtained using the Dermatology Life Quality Index (DLQI). A cost minimisation approach was used to compare the costs of all skin care approaches.

**Results:** No consistent differences were found in the severity of skin reactions or levels of discomfort suffered by patients in each of the 3 groups. Neither of the preventative' creams conferred any benefit. Patients who smoked were significantly more likely to develop skin reactions than non-smokers. Patients who were randomised to hydrogel dressings took longer to heal than those who applied dry dressings.

**Conclusions:** There is no evidence to support the prophylactic application of either of the creams tested for the prevention of radiation skin reactions. Dry dressings appear to be at least as effective as hydrogel dressings in the management of moist desquamation. This study, the largest randomised trial of skin care in radiotherapy so far, has generated detailed data (both subjective and objective) on acute radiation skin reactions.

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## Nutrition & patient outcomes: prospective randomised controlled trial in head-neck cancer patients undergoing radiotherapy

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**Rationale:** In a prospective randomised controlled trial we have shown that nutrition intervention significantly increases oral intake. We further investigated whether nutritional counselling or commercial supplements affected predefined patients' outcomes: nutritional status & Quality of Life (QoL).

**Methods:** Sample size was determined for 85% power, 1% significance. There were 75 head-neck cancer outpatients (pts) stratified by cancer staging: 25 (G1) received individualised nutritional counselling with foodstuffs, 25 (G2) high protein liquid supplements and 25 (G3) an *ad lib* intake. Compliance was weekly monitored. Nutritional status (Ottery's Subjective Global Assessment) and QoL (EORTC) were evaluated at the onset, at the end and 3 months after radiotherapy (RT). ANOVA stratified by stage and adjusted for symptoms and disease outcome was used for comparisons.

**Results:** At baseline, malnutrition was observed in 56% stage III/IV and 4% I/II pts, p=0.004. During RT, nutritional deterioration occurred in 29%

G1 and 37% G2, already malnourished, and in 96% G3 pts. In G1, all QoL scores improved ($p \leq 0.001$) proportionally to increased energy/protein intake ($p<0.003$), yet pain/discomfort worsened in association with anorexia ($p=0.07$) and dysphagia/odynophagia ($p=0.05$). In G2, all function scores improved ($p<0.03$); pain/discomfort worsened in association with anorexia ($p<0.001$) and dysphagia/odynophagia ($p=0.008$). All QoL scores worsened in G3. At 3-months follow-up nutritional status was maintained/improved in 88% G1, good QoL was reported by all G1 pts. Only 59% G2 and 31% G3 maintained nutritional status, whilst overall QoL deteriorated in G2 ($p=0.05$) and G3 ($p=0.001$).

**Conclusions:** During RT individualised counselling and supplements improved nutritional status and QoL. In the medium term, patient outcomes were only consistently improved by individualised nutrition education and adherence to adequate diets.

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## Psychological and social aspects of survival of childhood cancer

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**Objectives:** The purpose of the study is to investigate the psychological and social aspects of survival of childhood cancer. More specifically, we examine if survivors are characterized by an increased tendency for anxiety, reduced sociality but also, we explore their personal views about the impact disease has had on their life.

**Methods:** 95 survivors (40 adolescents and 55 young adults) were examined. A sample of 100 young people was used as control. a) The Spielberger questionnaire was used for assessing anxiety. It is constructed by two subscales, the first (State) referring to anxiety as presenting condition and the second (Trait) referring to anxiety as personality trait. b) The standardized SF-36 quality of life scale was administered. This is a 36-item short-form. In the present study, we measured the scale of social functioning, which refers to the limitations in social activities because of physical or emotional problems. c) A semi-structured questionnaire was also administered where these young people focus on the differences, which possibly exist between them and other people of the same age. The survivors, also, analyze the way in which cancer has influenced their life.

**Results:** Anxiety is present in a significant percentage of this population. The mean scores for both subscales are higher in survivors ($p< 0,05$), especially in Trait, which is more representative of anxious personality. In terms of sociality, there is not any statistically significant difference between the two samples. On the contrary, survivors show more interest and compassion for others' problems. They are popular and have greater expectations from their relationships. Survivors feel they are different from other people of the same age, sometimes in a positive way. They may feel they are more vulnerable physically, but they believe they are more mature and. Additionally, they feel that disease has changed their attitude on life and their goals.

**Conclusion:** The experience of cancer in childhood changes the whole life of survivors, influencing the process of their maturation. Even if they do not exist major differences in physical ability, survivors express greater stress and many worries for their future health. On the contrary, they also attribute some positive outcomes to the experience of the disease, such as their early maturation, their greater interest for other people and their ability to fight for their goals.

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## Impact of the nutritional status in geriatric oncology

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**Background:** The management of elderly cancer patients requires a multidimensional assessment to detect and to quantify medical and non-medical conditions which can interfere with cancer and its treatment. We have developed a minimal comprehensive geriatric assessment (mini-CGA) to prospectively evaluate the global health status of elderly cancer patients who are treated at our Cancer Centre. We present our data on one of the most important aspect of this assessment: the nutritional status of this very particular population.

**Patients and methods:** During the mini-CGA, patients met a dietician who assessed their nutritional status. Collected data included weight loss (bwl) during the last 3 months, caloric and protein intake, Mini Nutritional Assessment (MNA® Nestlé). In addition, we collected informations concerning their social and lifestyle status, their functional status (Activities of Daily Living and Instrumental Activities of Daily Living; ADL and IADL score), and comorbidity (CIRS-G). Pearson's $\chi^2$ test was used to examine relationship between MNA and qualitative values. Survival time was defined as the time from the mini-CGA to the date of death or last follow-up. A Cox proportional hazards regression model was used to estimate the hazards ratio (HR) and 95 percent confidence intervals (95%CI) for significant risk factors of death with regard to malnutrition and others parameters.

**Results:** One hundred nineteen pts (64% male, 55% hospitalised) were evaluated from 05/99 to 07/01. Median age was 78 years (range: 66-92). Major tumour sites were prostate (55%) and breast (44%). Ninety-six pts (90%) had progressive disease, and 49 (41%) had metastatic evolution. Forty-six pts (42%) were fully independent in ADL (score=6), but only 13 pts (12%) in IADL (score=14). Fifty-seven pts (55%) had mild to severe disability/morbidity status (CIRS-G severity index $\geq$ 2). Only 31% pts were estimated well nourished (MNA >23.5), the body weight loss was $\geq$ 5% in 40% pts. A good nutritional status (MNA >23.5) was significantly associated with functional independence in ADL*, and absence of metastases** (* $p<0.001$,** $p<0.05$). Median survival time was 7 months (95%CI 5-9 months). In univariate analysis, metastatic status, MNA, ADL score and CIRS-G severity index were significantly correlated with overall survival (OS). In multivariate analysis, MNA<23.5 (HR=4.1, 95% CI: 2.2-7.8), CIRS-G severity index $\geq$ 2 (HR=2.5, 95%CI: 1.5-4.2) and ADL score <6 (HR=2.3, 95%CI: 1.3-3.9), were found to be independent prognostic factors for shorter OS.

**Conclusion:** These data show that nutritional status, ADL dependence and co-morbidity should interfere with survival independently of cancer status. Thus, these parameters must be taken into account for treatment decision making.

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## Massage and aromatherapy massage for symptom relief in patients with cancer: a Cochrane systematic review

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**Background:** Aromatherapy massage is reported as the most commonly used complementary therapy in the health service and is employed in cancer and palliative care largely to improve patients' quality of life and reduce psychological distress. The aim of the systematic review is to investigate whether aromatherapy and/or massage decreases psychological morbidity, lessens symptom distress and/or improves the quality of life in patients with a diagnosis of cancer in the short and/or long term.

**Methods:** A comprehensive search strategy has been developed for identification of relevant studies, utilising databases including; The Cochrane Controlled Trials Register, Database of the Cochrane Complementary Medicine Field, MEDLINE, CINAHL, British Nursing Index, EMBASE, AMED, PsycINFO, SIGLE, CancerLit, Dissertation Abstracts International. Experts in the field of complementary therapies are being contacted and a hand search of relevant journals undertaken.

**Results:** 1322 references were retrieved from the searches. Two reviewers independently screened the references, excluding 1310, including 9 and no decision being possible on 3 due to lack of available information. The 9 included references represented 7 studies, all of which were randomised controlled trials. Analysis of the evidence presented by these trials is underway.

**Conclusions:** Despite a plethora of anecdotal evidence and case study reports supporting the use of aromatherapy and massage in cancer care, this review has identified 7 studies of massage and aromatherapy massage in patients with cancer that stand up to rigorous methodological scrutiny. The included studies will be presented and discussed.