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Nutrition intervention: a prospective randomised controlled trial in colorectal cancer patients undergoing radiotherapy

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Rationale: In cancer, the benefit of nutrition with or without supplementation is as yet unproven.

Methods: In a prospective block randomised controlled trial, the effect of individualised nutritional counselling or commercial supplements on oral intake was investigated. There were 111 colorectal cancer outpatients (pts), 70M:41F, age 66± 10(33-94) yrs, stratified by cancer staging; 37 (G1) were assigned to receive individualised nutritional counselling based on current foodstuffs, 37 (G2) to high protein liquid supplements and 37 (G3) to *ad lib* intake. Compliance was weekly monitored. Nutritional intake was assessed by a 24hr recall questionnaire at the onset, at the end and 3 months after RT; total energy requirements (ER) were = estimated basal requirements × 1.2 activity factor, protein intake was compared to reference. ANOVA stratified by staging and adjusted for symptoms was used for group comparisons.

Results: Baseline intake was similar in the 3 groups; energy was higher than ER (NS), protein was lower than needs, p=0.06. During RT, >90% pts experienced increased diarrhoea (p=0.009), nausea (p=0.003), anorexia (p=0.002); symptoms were worse in staging III/IV, p=0.01. At the end of RT by comparison to the onset, energy intake increased in G1 (555 kcal/d, p=0.002) and G2 (296 kcal/d, p=0.04); G1>G2, p=0.001; protein intake increased in G1 (27g/d, p=0.007) and G2 (30g/d, p=0.001); G1<G2, NS; the increase was always higher in stage I/II, p=0.05. Energy/protein intake decreased in G3, p<0.001. At 3 months follow-up, G1 pts still complied with nutritional recommendations and maintained energy/protein intake; whilst in G2/G3 intake decreased, either to baseline (staging I/II) or below baseline, p=0.056 (staging III/IV).

Conclusions: Despite the RT induced symptoms, counselling and supplementation did improve patients' intake, though more effectively in early stages. During RT, both interventions were effective protein intake restorers; individualised counselling and education was the optimal nutrition intervention, and the only to assure a sustained adequate diet in the medium-term.

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Effect of amifostine to prevent radiotherapy-induced acute and late toxicity in head and neck cancer patients who had normal or mild impaired salivary gland function

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Background: Amifostine as the radioprotective agent, did not show the benefit in reducing the xerostomia in every head & neck cancer patients, but depending on the total radiation dose and the volume of the salivary gland in the treated area.

In this multi-centers, randomized study, we decided to show that Amifostine has reduced the acute radiation toxicities in the patients who had normal or mild impaired salivary gland function and returned the normal salivary gland function in the long-term follow-up. In addition we tried to know how often and severity that the nausea and vomiting had occurred without the prophylaxis anti-emetic.

Materials & Methods: There were sixty-seven head & neck cancer patients, were randomized to have radiotherapy (control group, n=35) or radiotherapy plus Amifostine (study group, n=32). All patients received the standard conventional radiotherapy. For the study group, the patients received Amifostine 200 mg/m2, intravenous infusion 30 minutes before radiation. No prophylaxis anti-emetic in the patients who had no experience of nausea and vomiting. The efficacy of the treatment were evaluated by the visual analog scales to a questionnaire which concern dryness of mouth and the oral comfort, the RTOG/EORTC acute/late radiation morbidity scoring criteria, the collection of the whole saliva and the 99mTc-pertecnetate scintigraphy of the salivary glands.

Results: We excluded 5 cases in control group who did not do the baseline salivary gland function or had severe salivary gland impairment. Amifostine reduced the severity and delay the time to have grade ≥ 2 toxicities. At the end of the treatment, the subjective evaluation showed that Amifostine reduced the visual analog score from 6.49 to 3.73 (P < 0.001) and reduced grade ≥ 2 mucositis from 75% to 24% (P= 0.002) and acute xerostomia from 82% to 39% (P =.001). In both arms the mucositis recovered within 3 months. After one year follow up, the chronic xerostomia was still present 30% in control group, but only 5% in study group (P=.047). The 99mTc-pertecnetate scintigraphy demonstrated that the salivary gland function returned to normal 36.3% in study group versus 9.1% in control group (P=.034). The nausea and vomiting occurred 64.5% in study group, but only 25.8% need 5HT3 antagonist therapy. There was only one patient who experience one episode of grade 2 hypotension. The median follow up time for control and study group were 20.8 and 25.3 months, respectively. There was no statistical difference in 2-year disease free survival.

Conclusion: Amifostine is effective to reduce the acute mucositis, acute and late xerostomia in head and neck cancer patients who had baseline normal salivary gland function with acceptable side effects and without anti-tumor effect. We suggest using the 99mTc-pertecnetate scintigraphy of the salivary glands to select the patients who will get the real benefit from the Amifostine.

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Neuropsychological functioning in women following adjuvant treatment for breast cancer

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Background: Recent research suggests that deficits in cognitive functioning may occur following adjuvant treatment for breast cancer. However, it is not clear whether deficits in cognitive function are due to chemotherapy and/or hormonal therapy (e.g. tamoxifen), or whether other factors such as psychological and disease morbidity may contribute to changes in neuropsychological function.

Materials and methods: A cohort of 150 women treated with i) adjuvant chemotherapy (standard versus sequential) and hormone treatment; ii) adjuvant chemotherapy alone, or iii) adjuvant hormone treatment alone were recruited into the study. Cognitive function was assessed using the Cognitive Drug Research (CDR) computerised assessment system. The tasks used were: Simple Reaction Time, Digit Vigilence, Complex Reaction Time, Numeric Working Memory, Immediate Word Recall, Delayed Word Recall, and Delayed Word Recognition. Pre-morbid ability was assessed using the National Adult Reading Test (NART). In addition questionnaires examining prospective memory, cognitive failures, anxiety and depression, and health-related quality of life were administered. Women were at least 6 months post-chemotherapy at time of assessment.

Results: A series of regressional analyses were conducted on preliminary data from 96 participants (mean age 54) who had undergone chemotherapy with or without tamoxifen. Results showed that longer durations of chemotherapy have a small but significant impact upon performance on the Delayed Recognition Task (p<.05), age, NART score, and emotional functioning were also significant predictors of Delayed Word Recognition. Time since treatment, tamoxifen, fatigue, anxiety, and pain did not predict cognitive performance on this task. However, the overall model had a poor fit (Adj. R^2=.20, F(9,87)=3.57, p < 0.001). A relationship between treatment related factors and cognitive performance was not found for the remaining CDR tasks.

Conclusions: In this series longer duration of chemotherapy results in poorer performance on a word recognition task. However, the broader impact on cognitive and emotional function of specific chemotherapeutic agents and duration of treatment need to be explored further.