1324 PUBLICATION

Treatment decision-related factors in cancer patients

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Purpose: To find out the factors on treatment preference in cancer patients and to figure out the differences of values on treatment between the physician, family member and patient.
Material and methods: We enrolled the cancer patients with advanced or terminal stage and distributed the questionnaire to the physician and family member and patient if family member permitted in Seoul National University Hospital. The questionnaire includes these questions: 1) treatment preference according to the burden of treatment (low: a few days of chemotherapy vs. high: one month of ventilator care in intensive care unit), side effect (death, physical impairment, cognitive impairment) and the probability of side effect (1, 25, 50, 75, 99%), 2) concordance rate of opinions between the physician, family member and patient
Result: Total 121 cases were enrolled. Of these, 116 physicians (95.9%), 75 family members (80.6%) and 23 patients' opinions (19%) were available. As the burden of treatment increases, the acceptance rate decreases. (97.4% vs 82.1% in physician, 93.3% vs 86.5% in family member, 87.0% vs 69.6% in patient). With regard to the side effect, the acceptance rate decreases in order of death, physical impairment and cognitive impairment. (97.4% vs 78.9% vs 42% in physician, 93.3% vs 81.7% vs 49.3% in family member, 87.0% vs 72.7% vs 59.1% in patient). As the probability of side effect increases, the acceptance of each treatment decreases in all three parts. The concordance rate of opinions on treatment decision is decreasing according to treatment burden. On treatment with high burden, the concordance rate between physician and patient is 52.9%. Also the concordance rate of opinions decreases in terms of side effect, i.e. in order of death, physical impairment and cognitive impairment. The concordance between physician and patient on cognitive impairment is only 25%. Regarding probability of side effect, the concordance is lowest when the probability of side effect is 50%.
Conclusion: Treatment preference depends on treatment burden, sort of side effect and the probability of such side effect. And the concordance rate of opinions of physician, family member and patients are various. To determine the treatment in cancer patients, values held by physician, family member and patient should be considered as well as treatment burden, sort of side effect and the probability of side effect.

1325 PUBLICATION

The dose-dense chemotherapy: is more frequently the better?

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Background: Pre-clinical cancer models support the Gompertian principle of faster doubling times in smaller tumors. According to this model, the Norton-Simon hypothesis suggests that the most effective strategy is to expose the tumor to cytotoxic agents as frequently as possible to minimize re-growth between cycles. The availability of hemopoietic growth factors makes this approach feasible. We reviewed data of trials evaluating the feasibility of dose-dense chemotherapy and the role of concomitant G-CSF support in the treatment of chemosensitive solid tumors and hematological malignancies.
Material and methods: The principal databases (PubMed, CancerLit, Medline) have been checked using keywords relative to dose-dense, CT and myelotoxicity, and considered only for the most representative papers on breast cancer and malignant lymphomas.
Results: *Breast cancer*: Some pilot trials with dose-dense regimens in the neo-adjuvant setting have not shown any evidence of better outcomes. However two phase II randomized trials comparing dose-dense vs. standard interval schedule, have shown the superiority of dose-dense schedule in terms of pathologic complete response and breast conservative surgery. In adjuvant setting the dose-dense approach was evaluated in three large prospective randomized phase III clinical trials comparing dose-dense approach with G-GSF vs. standard interval treatment in pts considered at high-risk of recurrence: two of these trials showed the superiority of dose-dense approach in terms of DFS and OS.
Non-Hodgkin Lymphoma: The German High-Grade NHL Study Group demonstrated that elderly pts receiving CHOP every 14 days did better in terms of TTF and OS with respect to pts receiving CHOP at the standard 21-day interval. Similar results on OS were observed in younger pts randomised to be given CHOP or CHOP-etoposide, every 14 or 21 days. The duration of G-CSF treatment in these studies ranges from 6 to 10 days, and G-CSF support did not increase the non-hematological toxicity
Conclusions: Further understanding of the biology and behaviour of tumour cells may lead to significant improvements in the long-term prognosis for patients with early and advanced breast cancer. Preliminary data on breast cancer and NHL support the use of G-CSF during dose-dense regimens. Dose-dense schedule is still an investigational approach. The use of Peg-filgrastim in a dose-dense schedule approach need to be addressed.

1326 PUBLICATION

The first use EORTC quality of life questionnaire H&N35 in Danish

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Background: The quality of life questionnaire EORTC C30 with the head and neck specific module H&N35 has been validated in many languages and cultural settings, but not in Danish. This validation was the purpose of the current study.
Materials and methods: In a cross sectional study 116 of 120 (97%) recurrence free head and neck cancer patients returned a valid questionnaire. The patients were attending follow up after single modality treatment with either radical radiotherapy (N = 83) or surgery (N = 33) for cancer of the larynx (N = 44), pharynx (N = 34) or oral cavity (N = 38). Mean age was 63 years (range 36–92) and median follow up was 20 months (range 1–65).
Results: The compliance was high with only 1.6% missing answers. Sixteen patients did not answer the items related to sexuality; not answering these questions was significantly dependent on high age. The psychometric properties of the questionnaire previously described were confirmed with the Danish translation: Construct validity was comparable with previous results. Compliance was excellent and overall internal consistency was acceptable to excellent. Most of the scales of the questionnaire were sensitive to influence from patient, tumour and treatment related factors: Twenty of 33 scales showed significant differences between patients with WHO performance status 0 and *1. Eight scales depended significantly on age, among them HN Dry Mouth. The absolute correlation coefficient was very low (< 0.36). Among significant findings, age was invariantly negatively correlated with the symptom scales and positively correlated with the function scales. Gender also significantly but weakly influenced 3 scales with women having the most symptoms. Seventeen of the 33 factors differed significantly between initial tumour sites. After excluding the patients who had surgery (mainly oral cavity cancers) 7 items differed according to site. The difference depending of site was only present in the stage 1+2 group, probably because the stage 3+4 patients had irradiation of almost the same areas at least to moderate doses. Stage was significantly and positively correlated with 10 scales. The irradiated patient had the worst symptoms in all scales – significant in 23 scales. Among irradiated patients improvement was observed with increasing time since therapy in 13 scales. Among the patients whom had surgery 5 pain related scales (Pain, HN Pain, Constipation, Pain Killer and HN Nutritional supplement) worsened with time since therapy. No improvement was observed in any scale among the patients who had surgery with longer follow up.
Conclusion: The EORTC H&N35 in conjunction with EORTC C30 is a valid and informative tool in assessing the quality of life of head and neck cancer patients, also in the Danish translation showing important differences depending on age, gender, tumour site, stage, treatment modality and time since therapy.

1327 PUBLICATION

Male Cancer Patients' attitudes towards female physicians, female nurses and chaperones during urological consultations

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Objective: There is considerable literature regarding female patients attitudes towards male physicians and chaperones. It is well known that some women have a strong preference for female physicians particularly during pelvic exams (Rifkin. Acad Med. 2002; 77:1034–8). On the other hand, even though a significant proportion of the health professionals are females, male cancer patients' attitudes and preferences have not been well studied (Gupta. Hum Resour Health. 2003 22; 1:5) (Chur-Hansen. J Adv Nurs. 2002; 37:192–8). Hence, as part of a service development audit, we assessed male urological cancer patients' attitudes towards female physicians, female nurses and chaperones.
Patients and methods: A random sample of 89 patients completed a self-administered anonymised questionnaire during their routine follow-up clinic visits. The median age group of the patients was 51–70yrs (Age group 18 to 30yrs – 8%; 31 to 50 yrs – 30%; 51 to 70 yrs – 39%; above 71yrs –23%). 40% of the patients had testicular cancer and 60% had prostate cancer.
Results: Overall, 96% of patients surveyed felt that their privacy has been respected in the clinic and 93% of the patients mentioned that they and

their partners have been given the opportunity to discuss any personal problems or worries.
A minority of male patients (prostate – 11%; testis – 11%) preferred to consult a male doctor. None of the patients expressed a preference for a female doctor. 10% of patients did not feel comfortable discussing personal/sexual issues with a female doctor. 56% of patients did not like the presence of a nurse during the consultation with the doctor. In particular, 12% patients did not feel comfortable discussing personal/sexual issues with a male doctor in the presence of a female chaperone.
Conclusion: Whenever feasible, male patients, like their female counterparts, should be offered the option of seeing a male health professional. Since an increasing proportion of physicians are likely to be females in the near future, these gender preferences of some males have implications for service delivery.

1328 PUBLICATION

The use of subcutaneous amifostine in the treatment of aerodigestive malignancies

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Background: We previously reported that Subcutaneous Amifostine (SQA) was safe and effective in decreasing the incidence of mucositis in 45 patients (pts) receiving chemoradiation (CR) or adjuvant radiotherapy (RT) in the treatment of head and neck cancer (HNC). Our expanded experience includes 13 additional pts with HNC, 4 with lung cancer (LC), and 2 with esophageal cancer (EC)
Methods: From May 2001 to October 2004, a total of 64 pts (57M, 7F, median age 57) were given SQA as a flat dose of 500 mg 30 minutes prior to daily RT. In HNC pts, CR was used in 26 (3 adjuvantly) and RT alone in 32. All pts with LC and EC received CR. Our protocol involves pre-medication with ondansetron and fexofenadine 60 mg bid or loratadine 10 mg qd. The median follow-up was 18 months.
Results: Overall, SQA was well-tolerated. Nausea and hypotension were rarely observed. Cutaneous reactions were seen in 12 pts (8 local, 4 systemic). The 4 pts with systemic reactions also developed fever and discontinued SQA. They were treated with antihistamines and recovered without sequelae. Subsequent pts were treated with rotating injection sites and routine administration of prophylactic antihistamines; 8 of these patients had self-limiting, localized skin reactions, and 0 had systemic reactions.

The results of pts treated with SQA

	HNC-CR (n = 26)	HNC-RT (n = 32)	LUNG (n = 4)	ESOPHAGUS (n = 2)
Treatment Break > 1 week	0	0	0	0
Gr. > 3 Mucositis	35%	16%	25%	0
% Weight Loss	13%	8%	8%	5%
PEG tubes	15%	6%	0	0
Gr.>2 pneumonitis	n/a	n/a	0	n/a
Hospitalizations	11%	6%	0	0
Alive and NED	100%	100%	75%	100%

Conclusions: This study confirms our prior experience that SQA is safe and effective for cytoprotection in pts with HNC treated with RT or CR. Our data also agree with other published reports showing the efficacy of SQA in the treatment of LC and EC. SQA is well tolerated with the proper premedication regimen. Acute and chronic CR and RT treatment-related toxicities decreased in frequency and severity in patients treated with amifostine compared to our historical controls.

1329 PUBLICATION

The EORTC core quality of life questionnaire (QLQ-c30 version 3.0 Turkish) in cancer patients under palliative radiotherapy

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Background: The aim of this study is to evaluate the reliability and validity of the questionnaire EORTC QLQ-C30 (Turkish version 3.0) obtained from patients treated with palliative radiotherapy and to compare the differences in patients' performance status with EORTC QLQ-C30 (Turkish version 3.0) questionnaire.
Methods: Eighty eight (88) patients with advanced malignant disease treated with palliative radiotherapy between September 2004 and December 2004 were included in the study. The patients were asked to complete the questionnaires before the start of radiotherapy and at the end of the radiotherapy. During the first phase, statistical analysis was performed to evaluate the validity based on the examination of correlation coefficients among the items and subscales. For the second phase, we calculated Cronbach's alpha coefficient for the functioning and symptom scales both for the pretreatment and the post treatment data to assess the reliability of the questionnaire. Additionally, the clinical parameters that physicians use for the assessment of performance status at pretreatment and post treatment phase (ECOG < 2, $\geqslant 2$) were analyzed by correlating for the EORTC QLQ C-30 with subscales.
Results: The mean age of the sample was 57 years (range 15–72 years). The majority of the patients (87.5%) had metastatic disease, and remaining patients (12.5%) had local advanced disease. Cronbach's alphas were calculated as 0.892, 0.896 for pre and post treatment phases respectively. Most interscale correlations were statistically significant ($p < 0.01$). Regarding performance status, those with a better one ($\leqslant 2$) reported statistically significant high level of functioning scales and low levels of all symptom scales in both the pretreatment and post treatment assessment. It was observed that patients with post treatment ECOG$\leqslant 2$ score reported significantly greater improvement than patients with post treatment ECOG > 2 score. The factor analysis resulted in 14 factors explained 88.85% of total variance.
Conclusion: The Turkish version of the EORTC QLQ C30 (version 3.0) is a valid and reliable questionnaire for Turkish cancer patients under palliative radiotherapy. The results of this study contributes to the impact of comprehensive palliative radiotherapy and its assessment.

1330 PUBLICATION

Nail toxicity associated with docetaxel-containing chemotherapy in patients with advanced gastric cancer

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Background: Since docetaxel has been widely used for the treatment of various tumors, nail toxicity becomes one of the most common toxicities of docetaxel-containing chemotherapy. Nail toxicity is important because it not only lowers the patient's quality of life but also affects the chemotherapy schedule and dosage. This study prospectively investigated the nail toxicity associated with docetaxel containing chemotherapy in patients with advanced gastric cancer (AGC).
Material and methods: Pathologically proven, chemo-naïve AGC patients were treated with one of the 4 chemotherapy regimens;
1. docetaxel 60~75 mg/m^2 i.v. on day 1 at 3-week intervals (D)
2. docetaxel 60~75 mg/m^2 and cisplatin 60 mg/m^2 i.v. on day 1 at 3-week intervals (DP)
3. docetaxel 60~75 mg/m^2 i.v. on day 1 and capecitabine 2000~2,500 mg/m^2/day p.o. on days 1–14 at 3-week intervals (DX)
4. docetaxel 60 mg/m^2 and cisplatin 60 mg/m^2 i.v. on day 1 and capecitabine 1,875 mg/m^2/day p.o. on days 1–14 at 3-week intervals (DXP).

All patients were prospectively assessed for toxicities with NCI-CTCAE version 3.0
Results: From October 2003 to March 2005, a total of 181 patients were enrolled. Sixty-one patients (33.7%) were treated with D regimen, 23 (12.7%) with DP regimen, 49 (27.1%) with DX regimen, and 48 (26.5%) with DXP regimen. One hundred and thirty patients (71.8%) experienced grade $\geqslant 1$ nail toxicity including 57 patients (31.5%) of grade $\geqslant 2$. At a cumulative docetaxel dose of 300 mg/m^2, the frequency of nail toxicity $\geqslant$ grade 2 was 7% with D regimen, 15% with DP regimen, 59% with DX regimen, and 44% with DXP regimen (log rank, $P < 0.0001$). A multivariate analysis of prognostic factors revealed that old age ($p = 0.046$; OR, 1.765; 95% CI, 1.010 to 3.086), poor performance status ($P = 0.036$; OR, 2.882; 95% CI, 1.070 to 7.766), and capecitabine-containing regimen ($P < 0.001$; OR, 7.032; 95% CI, 3.255 to 15.190) were independent poor risk factors for nail toxicity $\geqslant$ grade 2.
Conclusions: Nail toxicity is a common toxicity associated with docetaxel-containing chemotherapy in patients with AGC. Patients with old age, poor performance status, or concomitant use of capecitabine in particular should pay attention to the development of severe nail toxicity with docetaxel-containing chemotherapy.