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POSTER

### Use of Amifostine (AMI) to reduce toxicity following Taxol-based chemotherapy in solid tumors. A randomized phase II study of the Hellenic Cooperative Oncology Group

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**Background:** Taxol is active against several tumors. Its major toxicities are myelosuppression, neurotoxicity, mucositis and hypersensitivity reactions. AMI has shown that diminishes the myelotoxic and non-hematologic toxicity of alkylating agents and platinum or platinum derivatives.

**Goal:** The goal of this randomized study is to investigate whether AMI can reduce the degree of treatment-related toxicity of Taxol.

**Patients and methods:** 150 patients with a variety of malignancies treated with Taxol-based chemotherapy, were randomized to receive or not AMI. The dose was 910 mgr/m<sup>2</sup> in a 10 min iv infusion prior of Taxol administration. Those who were previously treated with Cisplatin or Taxanes were excluded from the study. Physical and neurologic examination was conducted before chemotherapy, after 3 cycles and 1 month after completion of it. Every possible toxicity was monitored according to NCI Common Toxicity Criteria.

**Results:** 78 patients received (Group A) and 71 did not receive (Group B) AMI. Hematologic toxicities were similar among the two groups except thrombocytopenia grade 2/3 which occurred in 7% in Group B vs 2% in Group A (p-value<0.05). Mucositis was observed in 9% in Group B vs 4% in Group A (p-value=0.056). Neurotoxicity occurred in 27% vs 18% of patients in Group B and Group A respectively (p-value=0.12). Grade 2 myalgias/artralgias occurred only in Group B (5%). Sensory neuropathy and abnormal tendon reflexes occurred mainly in Group B. Pathological evaluation of autonomic nervous system was observed in 14% of Group B vs 2% of Group A. Cerebral function was abnormal during treatment only in Group B (6%). 8% of the patients who received AMI exhibited nausea/vomiting and hypotension grade 2/3.

**Conclusion:** The data above shows that there is a trend in favor of Amifostine for the protection of peripheral neuropathy, mucositis and thrombocytopenia for patients receiving Taxol-based chemotherapy. Amifostine can be administered safely in an outpatient basis.

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### Rectal bleeding following 3D conformal radiotherapy for prostate carcinoma; a case-control quality of life study

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**Purpose:** 3DCRT for localised prostate cancer has facilitated dose escalation. The impact of rectal complications on anorectal Quality of Life (ARQOL) has not been evaluated. In a prospective randomised trial testing duration of neo-adjuvant hormonal therapy we carried out a matched case-control study comparing ARQOL in patients with/without rectal bleeding as a component of rectal complications. Methods: The Rectal Bleeding Quality of Life Scale (RBQOLS) as devised by Dent et al was sent to 69 patients. This questionnaire consists of 17 statements relating to the impact of bleeding on QoL. The patient, using a Visual Analogue Scale, scores each statement, higher scores indicating worse QoL. 19 cases with rectal bleeding post radical RT, 31 non-bleeding controls and 19 non-irradiated controls, were matched for T stage, Gleason score, age and pre-treatment PSA. 62 patients responded (91%). All patients had biopsy proven T1-3N0M0 prostatic adenocarcinoma and had completed either 4 (22 pts) or 8 (25 pts) months of neo-adjuvant maximum androgen blockade. Radiotherapy consisted of 70 Gy in 35 fractions using 2D (12pts) or 3DCRT (36 pts) with 3 fields and 10-15 MV photon beams. Results: See table.

Duration of hormones (mths)	Cases						Total
	Irradiated Controls			Non-Irradiated Controls			
	4	8	Total	4	8	Total	
n	9	10	19	13	15	28	15
Mean age, yr.s (SD)	67	66	66	68	69	69	64
Mean RBQOL score (SD)	11	16	14	13	8	11	0.78

**Conclusion:** Following hormone and radiation therapy for localised prostate cancer rectal bleeding does not have a statistically significant impact on ARQOL (2-sided t-test p=0.69), compared to non-bleeding irradiated patients. The irradiated controls had worse ARQOL scores than non-irradiated controls but this did not reach statistical significance. Use

of ARQOL instruments may quantify more accurately the impact of rectal toxicity than toxicity scores that focus on objective events.

## Palliative care

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### Quality assurance for improved co-operation between a palliative care team and general practitioner

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Interface is a "second line" home palliative care team. It provides specialised advice and dispenses certain complex treatments at the request and with the agreement of first line care dispensers. The quality of its services depends on the level of co-operation it establishes with the general practitioner. To ensure satisfaction and establish good co-operation with the general practitioner, Interface's activity must be multidimensional and include availability, competence, regard for the general practitioner's role and adequate initial and ongoing information.

To explore these dimensions, Interface conducted a satisfaction survey of the general practitioner of each patient followed from 1st January 2000 through to 15 February 2001. The team concurrently responded to a mirror questionnaire assessing the quality of its services and its interaction with the general practitioner.

Of the 97 questionnaires sent to the general practitioners, 56 questionnaires were collected and 49 were usable. The survey results indicate the degrees of satisfaction with the various services rendered by Interface. The performance of each dimension is rated according to the importance given to it.

Overall, the general practitioners are satisfied with the services dispensed by Interface. They consider as important and efficient the technical actions, medical support, psychosocial support, availability and speed of intervention of the nurse. They consider as important but not very efficient the information received, the regard shown for their role and their participation in decisions. The results of the mirror survey differ. Interface is less satisfied with its services than the general practitioner, qualifies as important and not very efficient the psychosocial support and medical support it provides. On the other hand, it considers as efficient and not very important the regard shown for the role and participation of the general practitioner.

Thanks to this study, Interface has identified the dimensions it must focus on to improve its co-operation with the general practitioner. The intervention procedures will be revised to ensure better information and greater regard for the role of the general practitioner. The divergent views of Interface and the general practitioner underline the need to involve him in the survey which, following revision of the procedures, will re-evaluate his degree of satisfaction.

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### Clinical prediction of survival and prospective evaluation of prognostic variables in terminally ill cancer patients

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**Purpose:** prognosis of terminally ill cancer patients is not as clear as in early stages of malignant diseases. A prospective analysis of various prognostic factors in terminally ill patients with solid tumours was carried out.

**Methods:** between September 1999 and February 2001 terminally ill cancer patients with solid tumours were eligible. All of them were not for active resuscitation and were receiving only palliative treatment. Clinical predictions of survival as well as recording of different parameters were carried out for each patient. Survival was calculated from date of DNR to date of death for any reason.

**Results:** A total of 162 patients were included. Mean time of survival was 41.5 days (median 10 days). Univariate analysis showed that absence of bone metastasis (P = 0.026), low albumin level (P = 0.017) and presence of delirium (P = 0.039), anorexia (p = 0.027) and Oedema (P = 0.016) had poor significant effect on survival. Multiple regression analysis showed that only low albumin and delirium were independent predictors of survival. Clinical prediction of survival was not accurately estimated in significant proportion of patients.

**Conclusion:** clinical prediction of survival is overestimated in significant number of terminally ill patients with solid tumours. Delirium and low albumin level were independent predictors of survival.