

for both scales. Interobserver variability was less using the ECOG scale. We conclude either scale could be used with good interobserver reliability. The ECOG scale minimises differences between observers.

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PUBLICATION

### Survival prediction in terminal cancer patients: Proposal of a model based on analytical variables

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**Objectives:** The prognosis of terminal cancer patients is usually determined by symptoms and scores in quality of life scales. Analytical data have not been commonly studied. We tried to identify analytical prognostic variables for survival in terminal patients with cancer.

**Patients and Method:** 316 patients and 22 analytical parameters were studied with regard to survival (blood count, renal and hepatic biochemistry, albumin and total proteins, cholesterol, ions, etc). The actuarial method was used to assess survival and survival comparisons were made with the log-rank test and the Breslow test. Step-wise regression analysis was then performed with the Cox method.

**Results:** The median survival was 26 days (295 patients have died and 21 remain alive). The univariate analysis found a relation between a short survival and the following parameters: hypoalbuminemia ( $p < 0.001$ ), hypocholesterolemia ( $p < 0.05$ ), lymphopenia ( $p < 0.001$ ), anemia ( $p < 0.001$ ), and increased values of LDH ( $p < 0.01$ ), alkaline phosphatase ( $p < 0.01$ ) and gamma-GT ( $p < 0.05$ ). The regression analysis confirmed the values of albumin, cholesterol, LDH and alkaline phosphatase as independent prognostic factor for survival in these patients.

The combination of albumin and LDH defined 3 groups of patients with different survival: 1) albumin  $> 3\text{g/dl}$  and LDH  $< 400\text{U/L}$ , median survival 41 days; 2) albumin  $< 3\text{g/dl}$  or LDH  $> 400\text{U/L}$ , 27 days; and 3) albumin  $< 3\text{g/dl}$  and LDH  $> 400\text{U/L}$ , 15 days ( $p < 0.000$ ).

**Conclusion:** The values of albumin and LDH may help define the prognosis in terminal patients with cancer.

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PUBLICATION

### Fatigue and quality of life (QoL) in cancer patients – Relations between haematological parameters and subjective assessment

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**Purpose:** Objective was to investigate relations between blood data and subjective experience of fatigue and QoL in cancer patients presently undergoing chemotherapy.

**Methods:** The present survey includes 58 cancer patients (21 colorectal, 23 bronchial, 14 ovarian cancer) with an average age of  $59.2 \pm 10.6$  years. According to their diagnosis all patients received individual chemotherapy. Fatigue was measured with the Multidimensional Fatigue Inventory (MFI), QoL with the EORTC QLQ-C30. These assessments were carried out immediately before each chemotherapy cycle. At the same time blood data (hemoglobin (Hb), leucocytes, thrombocytes etc.) were collected.

**Results:** Except for the first chemotherapy cycle, correlations between Hb and subscales of MFI were moderately high (Hb with general fatigue:  $r = -0.44$  at cycle 2,  $r = -0.44$  at cycle 3). Significant correlations were also found between Hb and certain EORTC QLQ-C30 subscales (Hb with global QoL:  $r = -0.50$  at cycle 2,  $r = -0.42$  at cycle 3).

**Conclusion:** In spite of the significant correlations found, results indicate that Hb-values yielded rather incomplete information about subjectively experienced fatigue and QoL in cancer patients.

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PUBLICATION

### Reirradiation with concomitant application of ethylol (amifostine) in recurrent pelvic tumors – First results from a phase II study

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**Purpose:** Unresectable recurrent carcinomas in preirradiated pelvic areas are a major problem for the radiooncologist because of exceeding the tolerance doses of bowel and bladder. Ethylol (Amifostine) has been shown to have a radioprotective effect on normal tissues. The aim of this prospective study is to evaluate whether the concomitant application of Ethylol (Amifostine) is able to reduce radiation associated side effects of pelvic high dose reirradiation.

**Methods:** Patients with a history of prior irradiation in the pelvic region at least 6 months before recurrence are included in the study. The study design consists of a pelvic reirradiation of the gross disease with a 2 cm margin to a dose of 39.6 Gy (1.8 Gy single dose). Additionally 500 mg Ethylol (Amifostine) are infused 20 minutes prior to irradiation. Toxicity and life quality are documented.

**Results:** 7 patients has been included in the study. All patients had a histologically confirmed pelvic recurrence of a gynecologic or rectal carcinoma. Of these patients 5 have completed therapy so far. No interruption of therapy was necessary. The acute radiation associated side effects were mild to moderate. No grade III/IV toxicities (EORTC/RTOG) were observed. Some episodes of nausea and hypotension due to amifostine were noted. All patients achieved a good palliative effect.

**Conclusion:** Our preliminary results indicate that high dose reirradiation of pelvic recurrences is feasible with a low rate of side effects and a good palliative effect.

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PUBLICATION

### Interest of bipulmonary irradiation combined with concomitant chemotherapy in treatment of pulmonary metastases

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Aim of the study was to evaluate the palliative effect of bipulmonary irradiation combined with CDDP (100 mg/m<sup>2</sup> Day 1) on dyspnea and performance status in patient with symptomatic bilateral pulmonary metastases.

**Patients and Methods:** From 05/92 to 03/98, 19 patients (sex ratio 3) with symptomatic and rapidly growing pulmonary metastases disease (Kidney: 7 cases, parotid gland: 4 cases, sarcoma: 3 cases, adenocarcinoma: 4 cases, hepatocarcinoma: 1 case) were treated in palliative intent with bipulmonary irradiation (6 Gy/2 fractions/2 days) and concomitant CDDP.

The same schedule was repeated every 4 weeks in case of clinical response up to a maximum of three cycles.

**Results:** The response was evaluated on the WHO performance status stage, WHO dyspnea score, and metastases measurement.

13 patients (70%) have had a significant improvement of dyspnea after 2 cycles. The performance status was improved in half of patients. No toxic death occurred.

**Conclusion:** Finally this regimen seems to be well tolerated, cost effectiveness and provide significant improvement of quality of life in advanced patients.

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PUBLICATION

### Analysis of the effect of chemotherapy (CT) on erythropoietin (EPO) synthesis in cancer patients (PTS)

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From June 95 to May 97 serum EPO levels were measured during CT treatment in 32 cancer pts. CT schedules used were: CDDP + VP-16 for small cell lung cancer (SCLC,  $n = 6$ ), BEP for germ cell tumours (GCT,  $n = 6$ ), CMF for breast cancer (BC,  $n = 10$ ), 5-FU + LV for colorectal cancer (CRC,  $n = 10$ ). Three serum EPO measurements were made (EPO-ELISA) coinciding with the 1st, 3rd, and final cycle given. The pts receiving CDDP (SCLC + G-CT) required transfusions due to G3-4 (WHO) anaemia and

were studied jointly. BC pts developed G1 anaemia but the pts with CRC developed virtually no anaemia.

#### Results:

	1st cycle	3rd cycle	Final cycle	P
<b>CDDP Group (n = 12)</b> Mean Hb (g/dl)	14.7 ± 1.6	10.4 ± 1.2	8.5 ± 1.2	p < 0.0001
Median EPO (mU/ml)	5.3	31.5	1.8	p < 0.0001
(range)	(1.2–20.0)	(1.8–73.0)	(0.2–10.8)	–
<b>CMF Group (n = 10)</b>				
Mean Hb (g/dl)	12.4 ± 0.7	12.2 ± 0.7	11.5 ± 0.8	p < 0.002
Median EPO (mU/ml)	4.0	8.0	4.1	p = NS
(range)	(1.0–48.0)	(3.1–89.0)	(1.6–33.0)	–
<b>5-FU + LV Group (n = 10)</b>				
Mean Hb (g/dl)	12.0 ± 0.8	12.4 ± 0.8	12.9 ± 1.1	p = 0.054
Median EPO (mU/ml)	7.5	12.5	18.5	p < 0.045
(range)	(2.5–22.0)	(2.4–276.0)	(5.0–600.0)	–

**Conclusions:** a) The cisplatin schedules analysed were associated with intense inhibition of the EPO response, b) The inhibition caused by CMF was less intense; c) 5-FU + LV seems to stimulate the synthesis of EPO.

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## PUBLICATION

### Epoetin alfa (EPO) prevents anaemia and improves quality of life (QOL) in cancer patients (PTS) undergoing platinum-based chemotherapy (CT)

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To evaluate the impact of EPO on anaemia secondary to platinum-based CT, 52 pts with small cell lung cancer (n = 27) or ovarian cancer (n = 8) were included from Jun-95 to Nov-97. CT consisted of 6 courses every 21–28 days (d) of one of these schedules: CDDP + VP-16, CBDCA + VP-16, CBDCA + CTX, CDDP + PTX. All pts were initially non-anaemic (Hb > 11.5 g/dl), and were separated into two groups depending on whether their Hb values fell to ≤11.5 g/dl after the first or second course (Group A) or not (Group B). Group A pts were then randomized to receive EPO 150 U/kg SC three times weekly, starting on the first day of CT (Group A<sub>EPO</sub>) or no EPO (Group A<sub>no EPO</sub>). The Nottingham Health Profile was used for QOL analysis, and 39 pts were evaluated (A<sub>EPO</sub> = 15, A<sub>no EPO</sub> = 11, B = 13).

#### Results:

Group	Initial Hb (mean ± SD)	Hb at inclusion (mean ± SD)	Final Hb (mean ± SD)	No. of pts transfused
A <sub>no EPO</sub> (n = 15)	12.8 ± 1.3	10.5 ± 0.8	8.8 ± 1.4	13 (87%)
p	NS	NS	<0.001	<0.001
A <sub>EPO</sub> (n = 20)	12.5 ± 1.2	10.5 ± 0.8	11.5 ± 1.8	4 (20%)
p	NS	<0.001	NS	–
B (n = 17)	13.4 ± 0.9	12.4 ± 0.7	11.5 ± 1.3	0

At inclusion no significant differences between groups were found in QOL, but at the end of treatment, it was increased significantly (p < 0.05) in groups A<sub>EPO</sub> and B versus group A<sub>no EPO</sub>.

**Conclusion:** EPO prevents anaemia, reducing the risk for transfusion and improves QOL in pts undergoing platinum-based cyclic CT.

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## PUBLICATION

### Palliation of bone metastases: A survey of patterns of practice in Canada

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**Purpose:** To determine the patterns of practice of radiation oncologists in Canada for the palliation of bone metastases.

**Methods:** A survey was sent to 300 practicing radiation oncologists in Canada. Five case scenarios with bone metastases were presented.

**Results:** A total of 172 questionnaires were returned (57%) for a total of 860 cases. 819 cases (95%) were treated with radiotherapy and 708 cases (82%) with external local fields (LF). Of those LF employed, doses ranged from a single 8 Gy to 30 Gy/10 fractions. 571 cases (81%) were treated with a short course of radiotherapy (a single 8 Gy – 17%, 20 Gy/5 fractions – 64%). 71 cases (10%) were treated with 30 Gy/10 fractions. With respect to the primary cancer: lung, breast and prostate, the proportions of using a single 8 Gy were 16%, 16% and 31% (p = 0.056); 20 Gy/5 fractions,

65%, 64% and 51% (p = 0.22); and 30 Gy/10 fractions, 9%, 12% and 5% (p = 0.16) respectively. Half body irradiation (HBI), and radionuclides were recommended more frequently in prostate cancer than in breast cancer (46/172 vs 4/172, p < 0.0001; 93/172 vs 10/172, p < 0.0001 respectively). Biophosphonates were recommended more frequently in breast cancer than in prostate cancer (13/172-7% vs 1/172 – 0.6%, p = 0.001).

**Conclusion:** LF remains the mainstay of therapy and the most common fractionation for bone metastases in Canada is 20 Gy in 5 fractions compared with 30 Gy/10 fractions in US. Despite randomized trials showing a single 8 Gy fraction is equivalent, the majority of us still advocate 5 fractions. There is a trend of utilizing HBI more in prostate cancer and biophosphonates in breast cancer.

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## PUBLICATION

### Quality of life (QoL) and treatment-related symptoms in postmenopausal women with metastatic breast cancer (MBC) during hormonal treatment (HT)

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**Purpose:** Multicenter national study in patients (p) with MBC receiving HT. Assessment of QoL in this subset of p. Specific survey of HT-related symptoms. Analysis of relation between QoL and HT. Patient's preference in MBC.

**Methods:** 226 p with MBC under HT were selected during a 9-month period. Two self-administered questionnaires were used: FACT-B for QoL and modified C-PET for symptoms (25 items). Centralised analysis of forms was carried out.

**Results:** Socio-demographic: 75% of p were older than 65 year and 92% had descendants and 42% reported sexual activity in last 12 months (m). HT: 50% antiestrogens, 27% aromatase-inhibitors and 24% progestins. Mean-time under HT was 15 m, being longer (21 m) for antiestrogens. The most frequent reported symptom was tiredness (79%), and 13 out of 25 symptoms were present in more than 50% of p (restlessness, decreased libido, depression, anxiety, muscle cramps, insomnia, constipation, weight gain, mouth-dryness, irritability, stress, difficulty to concentrate). Self-reported (SR) QoL, ranging 0 to 6 shows a mean of 3.77 with SD 0.51 and only 17.7% of p consider as bad (0–2) their QoL while 37.1% of p rate QoL as good or excellent (5–6). P receiving antiestrogens and with more than 12 m in HT report better QoL. For FACT-B subscales (quantitative value 0–4) means were physical 2.99, social/family 2.56, relationship with doctor 3.37, emotional 1.67, functional 2.15, other concerns 2.11. P with antiestrogens HT showed a better physical subscale and this domain shows a significant correlation with self-reported QoL.

**Conclusions:** Majority of MBC postmenopausal women under HT report many symptoms in a systematic surveillance. Intensity is predominantly mild. Mena SR-QoL is 3.77 (0–6 scale) being better for antiestrogens and for p with longer HT. For FACT-B better means were observed in relationship with doctor and social/family well being domains but physical well-being seems to show better correlation with SR-QoL. Lower score was obtained in emotional well-being. SR-QoL seems to be a consistent summary measurement that correlates with symptoms and specific tool (FACT-B). First-line HT and length of treatment (response) seems to correlate with better QoL.

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## PUBLICATION

### Should the depression sub scale of the Hospital anxiety and Depression scale be used as a screen for depression in patients with advanced metastatic cancer?

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**Introduction:** The Hospital Anxiety and Depression scale (HAD) is used in outpatient clinics and elsewhere as a screen for depression in patients with advanced metastatic disease, using pre established cut off thresholds of 8 for all possible cases and 11 for all probable cases of depression. However the HAD has not been validated for use in this population and previous studies have suggested it does not perform equally when used in patients with differing disease status.

**Aims:** The aims of the study were to determine the efficacy of the depression sub scale in patients with advanced metastatic disease.

**Method:** Patients with a diagnosis of advanced metastatic cancer were asked to complete the HAD scale and were also interviewed by using the Present State Examination.