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The development of a prediction index for patients at high risk of severe chemotherapy induced nausea and vomiting

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Background: Despite modern antiemetic therapy, 20% to 40% of cancer patients receiving chemotherapy fail to achieve complete control of emesis. Several risk factors for acute and delayed emesis have been identified; these include female gender, daily alcohol intake, chemotherapy emetogenicity and tumour type. We conducted a prospective cohort study to identify risk factors associated with the development of acute and delayed nausea/vomiting in patients receiving chemotherapy. With these data two prediction indices were developed in order to identify a priori patients at high risk for nausea/vomiting.
Materials and methods: Two hundred patients receiving outpatient chemotherapy were asked to complete a questionnaire assessing presence of risk factors prior to their first cycle of chemotherapy. Patients completed diaries tracking their nausea and vomiting using the National Cancer Institute of Canada Common Toxicity Criteria. Outcomes were collected following each cycle of chemotherapy up to 6 cycles. To determine which factors were associated with severe acute and delayed nausea/vomiting, multivariable logistic regression analysis adjusted for clustering was used. Initial variables for model inclusion were based on univariate selection process with an $\alpha = 0.25$. The likelihood ratio test in a backward elimination process was then used to select the final covariates into the model. Based on the regression models, two prediction indices were developed, one for severe acute emesis and one for severe delayed emesis. Risk score categories were calculated along with the area under the receiver operator curve (AUROC).
Results: The 200 cancer patients enrolled completed 864 cycles of chemotherapy. Mean age was 58. The median cycles of chemotherapy completed was 3. Incidence of severe acute nausea/vomiting was 7.2% (62 of 864 chemo cycles). Incidence of severe delayed nausea/vomiting was 9.3% (80 of 864 chemo cycles). On multivariate analysis for acute and delayed emesis, 5 factors were identified for acute (age, comorbidity, chemotherapy, alcohol intake, antiemetics) and 8 for delayed (age, comorbidity, chemotherapy, alcohol, cycle, acute vomiting, antiemetics). Based on these regression models, two prediction indices were developed, one for acute and one for delayed n/v. AUROC was 0.84 (95%CI: 0.78–0.89) and 0.79(95%CI: 0.74–0.88), respectively.

Question	n	r[a]	p-value	Compliance[b]
1. MTS – past 24 hrs	146	0.68	<0.001	80%
2a. MTS – sleeping	145	0.50	<0.001	79%
2b. MTS – swallowing	144	0.66	<0.001	80%
2c. MTS – drinking	144	0.63	<0.001	79%
2d. MTS – eating	141	0.63	<0.001	78%
2e. MTS – talking	144	0.68	<0.001	79%
2f. MTS – entertainment	121	0.36	<0.001	71%
2g. MTS – brushing teeth	134	0.52	<0.001	76%
2h. MTS – kissing	114	0.35	<0.001	67%
2i. MTS – leaving home	106	0.21	0.031	63%
2j. MTS – getting together	115	0.34	<0.001	68%
4. Overall MTS	144	0.57	<0.001	80%
5. Bowel movements	146	−0.01	0.939	80%
8a. DRA – sleeping	107	0.21	0.027	55%
8b. DRA – drinking	107	0.18	0.064	54%
8c. DRA – eating	103	0.20	0.042	52%
8d. DRA – entertainment	90	0.18	0.090	48%
8e. DRA – Taking care of yourself	99	0.32	0.001	51%
8f. DRA – getting together	84	0.21	0.055	45%
8g. DRA – leaving home	72	0.03	0.802	40%
9. Overall discomfort	111	0.01	0.904	56%
10.Overall health	143	−0.32	<0.001	80%

[a]Pearson correlation for OMDQ score and WHO mucositis grade on day 14.
[b]Overall mean compliance for all study days.

Conclusion: To our knowledge, such indices for prediction of high risk emesis are the first in oncology. These tools can be used to identify a priori patients at high risk for n/v and allow optimization of their antiemetic therapy. External validation of the indices is currently ongoing.

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Prevention of anemia by early intervention with once weekly epoetin-alfa during platinum-based chemotherapy

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Background: There is good evidence that epoietin alfa (Eprex®, EPO) is effective in treating moderate to severe anemia during cytotoxic cancer treatment. Further research is required to clarify its role in the treatment of mild anemia and the prevention of anemia in this setting.
Materials and methods: In a randomised, multicentre trial the effects of EPO on hemoglobin (Hb) levels and the need for bloodtransfusions (BT) were assessed in cancer patients started on chemotherapy (CT). Pts with Hb $\leqslant$ 2.1 g/dl and likely to receive CT for at least 12 weeks, were randomised (1:1) to EPO (40.000 U QW) to be started with CT simultaneously (early EPO) or when Hb dropped below 10.1 g/dl. (standard EPO).
Results: A pre-planned interim analysis was performed after 36 pts (18 early EPO vs 18 standard EPO) were enrolled. All pts entered the study before platinum containing CT was started. Data were obtained from the first 12 weeks of therapy. Both treatment groups were comparable for gender, age, performance score and tumor type. Mean Hb at baseline was 11.3 g/dl in both groups. EPO was started at an average Hb value of 11.4 and 9.8 g/dl respectively. Hb values in the early treatment groups increased significantly after week 3, 6 and 10. A global decrease was observed in the standard EPO group after week 2. Changes in Hb values between the 2 treatment groups became significantly different after week 3, 6, 8 and 10. No significant difference was observed in the number of BT's after early vs standard EPO treatment (1 BT in the early treatment group and 3 BT's in the standard treatment group). EPO treatment was well tolerated and no difference in the number of AE's were detected between the groups. Most of the AE's were as expected in a population of cancer patients treated with CT.
Conclusion: EPO treatment for mild anemia upon start of platinum-based CT when Hb becomes $\leqslant$ 12.1 g/dl, increases Hb values and results in significantly higher Hb values as compared to standard EPO therapy initiated when Hb drops below 10.1 g/dl. Maintaining Hb values around 12.1 g/dl may have a positive impact on quality of life according to several literature reports on this topic.

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Fractures negatively impact survival in patients with multiple myeloma or bone metastases from solid tumors

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Background: Patients with malignant bone disease are at high risk of developing multiple skeletal complications, including pathologic fractures, and these skeletal complications contribute to the poor prognosis for these patients. To assess the effect of fractures on survival in patients with multiple myeloma or bone metastases from prostate cancer or lung cancer and other solid tumors, we conducted a retrospective analysis of survival for patients in 3 large, randomized, controlled trials of zoledronic acid based on the occurrence of pathologic fractures on study.
Material and methods: A Cox regression model using fractures as a time-dependent variable was performed in patients with multiple myeloma (N = 513) or bone metastases from prostate cancer (N = 640) or lung cancer and other solid tumors (N = 766) who received 4 mg or 8/4 mg zoledronic acid, pamidronate (multiple myeloma), or placebo (prostate cancer or lung cancer and other solid tumors) every 3 to 4 weeks for up to 21 to 24 months. Treatment was also included in the model. Time to death was defined as the time from randomization to the final visit. Patients were censored at the final visit if death was not observed by end of study. Data from the core and extension phases were included in the analyses and all analyses were performed on the safety-evaluable population.
Results: Patients with multiple myeloma or bone metastases from prostate cancer who did not experience a fracture on study had better survival outcomes compared with patients who did experience a fracture on study. Overall, 43% of multiple myeloma patients experienced a fracture on study, and these patients had a trend of shorter survival with a hazard ratio of 1.304 (95% CI = 0.789, 2.156; P = 0.30) compared with patients who did not experience a fracture on study. In the study of prostate cancer patients, 19%