linear for all parameters studied and that no exponentiel increase in costs per YLG can be expected.
Discussion: Trials comparing these two regimens are nonexistent in the medical literature. Thus, the model had to be based on open trials, comparative trials with other comparators, and review articles. With this information, FLU appears to be a cost-effective alternative in the treatment of CLL. This model could be verified in a retrospective case review study or preferably a prospective study. In view of FLU superior tolerance profile, especially regarding vomiting and alopecia, the use of a quality of life instrument in a comparative trial would add important information.

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PP43. Quality of life assessments of patients with non-small cell lung cancer receiving Gemcitabine (Gemzar™) and Cisplatin

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Background: Traditional assessment of therapy for cancer has involved objective measurements of efficacy and safety. More recent interest in the patient's perception of therapy has led to the addition of quality of life (QoL) assessments to clinical trials.
Methods: QoL was assessed in a multicenter phase II trial of chemonaive patients with non-small cell lung cancer (NSCLC) receiving gemcitabine (1200 mg/m² weekly times 3 every 28 days) plus cisplatin (100 mg/m² every 28 days). QoL was assessed using the EORTC QLQ-C30 at baseline and at the end of each cycle.
Results: Thirty-eight patients completed 170 questionnaires (median = 4.5). For all patients, mean scores for the functional scales did not change significantly ($p<0.05$) from baseline, except for a decrease in role functioning after cycle 1. However, when comparing responders (n = 18) to nonresponders (NRs) (n = 18), change from baseline was statistically different for cognitive functioning after cycle 2, with responders improving and NRs worsening. For all patients, mean scores for symptom scales changed significantly for nausea/vomiting (N/V), pain, and dyspnea. N/V scores worsened after cycles 1, 2, and 4; pain scores improved after cycle 2; and dyspnea scores improved after cycle 3. When analysing only responders, significant changes from baseline were noted with worsening of N/V scores only after cycle 1 and with improvement of pain scores after cycles 1 through 4. When comparing responders to NRs, changes from baseline were statistically different for fatigue and pain scores. For both fatigue and pain scales, responders showed improvement, while NRs showed worsening.
Discussion: Overall compliance for completion of QoL questionnaires was relatively high considering patients received a median of 5 cycles of chemotherapy. Two of the 38 patients were not evaluated for tumor response so they were not included in the comparative analysis. Statistical analyses are limited by the small patient population and by interpatient variability of scores. Despite the toxicities commonly associated with chemotherapy, QoL did not decrease in NSCLC patients receiving gemcitabine and cisplatin, irrespective of response to therapy. Although patients experienced N/V, this is expected with cisplatin therapy. Disease symptomatology improved for those patients who responded to therapy.

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PP44. Cost-quality of life study in advanced no metastatic breast cancer patients treated by a high dose chemotherapy with sequential reinfusion of blood stem cells

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Background: The aim of this study was to measure the impact, in terms of quality of life (QL) and costs, of a high dose intensity chemotherapy associating cyclosphosphamide (3000 mg/m²) and doxorubicin (75 mg/m²) with RH G-CSF and blood stem cells+radiotherapy on no metastatic breast cancer patients (pts) with 4 to 10 axillary lymph nodes involved. Contrary to "classical" autograft, the intensive chemotherapy does not require isolation of pts in sterile room and may be administered with a minimal hospitalization. However, it seemed necessary to evaluate the burden for the pts of such a new modality of administration of high dose chemotherapy.
Methods: The QL study was carried out in the medical oncology unit of the Paoli-Calmettes Institute (Marseilles - France) between 04/1995 and 03/1997. Chemotherapy toxicity was evaluated by a self-administered questionnaire measuring the prevalence, duration/severity and distress level of 19 physical symptoms at 2nd and 4th cycles. Pts' QL was measured by the EORTC QLQ-C30 at the inclusion onto the protocol, the last cycle of chemotherapy and the end of radiotherapy. The same evaluation was pursued 3 and 6 months after the end of chemotherapy and 1 and 2 years later. The cost of treatment was assessed by using the standard economic analysis in health care. Direct medical costs were estimated by measuring the physical quantities of capital and labour consumed by each pt during chemotherapy+radiotherapy. Cost factors included pharmacy (chemotherapy, hematopoetic growth factor, antiemetic prophylaxis, intravenous antibiotic drugs and antifungal agents, blood products), laboratory tests, blood stem cells collection, hospitalization (supplies, staff costs, equipment depreciation, 'hotel' costs) in the medical oncology unit and outpatient clinic.
Results: All the 51 pts asked to participate to the QL study agreed and overall pts' compliance rate to questionnaires during treatment phase was 82%. Frequency of symptoms experienced by pts in 82 cycles of chemotherapy was high. Tiredness was reported in 98% of cycles, nausea in 74%, lack of appetite in 70%, fever in 65%, mucitis in 60% and vomiting in 50%. Alopecia was complete for 76% of pts after the 3rd cycle. The most distressing symptoms were cystitis, hair loss, vomiting, nausea, mucitis and tiredness. At the end of chemotherapy, all EORTC QLQ-C30 functional scales scores (including global QL score) were statistically significantly lower than baseline scores ($p<0.01$, for all statistics). But, at the end of radiotherapy, only physical functioning score was statistically lower ($p<0.05$) than baseline score. There was no statistically significant difference in all QL measures between baseline and 3 months after treatment. The mean cost of the treatment, assessed on 24 pts, was 90 327 FF. Main cost factors were : G-CSF (33%), hospitalization (28%), laboratory tests (16%) and radiotherapy (10%). The average cost of chemotherapy alone was only 2 734 FF (3%).
Discussion: Sequential QL self-assessment provided a quantitative estimate of the subjective impact of high dose chemotherapy with sequential reinfusion of blood stem cells. This study demonstrates that repeated QL measures can be possible with an acceptable rate of missing data. High dose chemotherapy had an clear adverse effect on self-assessed QL. However, three months after completion of the treatment, pts retrieved their preinclusion QL. Furthermore, as compared to "classical" autograft, this treatment allows a reduction of high dose chemotherapy cost of about 40%.

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