Psychosocial and economical aspects of cancer

848 POSTER

The development of a model of outpatient chemotherapy throughput - chemotherapy basic treatment equivalent (CBTE)

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Purpose: 1. To study the patient-, tumour- and treatment-related factors that significantly impact on treatment episode duration for outpatient chemotherapy treatment delivery. 2. To develop a new measure of outpatient chemotherapy throughput that considers variations in complexity compared with the older measures of patients treated per day.

Methods: A pilot study in our institution randomly measured the duration of outpatient chemotherapy delivery. Patient, tumour and treatment factors were collected and assessed for their impact on treatment duration using multivariate analysis. A new model of outpatient chemotherapy was then developed using various modeling processes.

Results: Treatment times of 266 occasions of service on 134 patients were collected. Median treatment duration was 124 minutes. Significant factors that impacted on treatment duration were the chemotherapy regimen, the type of infusion, patient age and whether the patients required a community nurse to be organized. A complexity measure was developed (Chemotherapy Basic Treatment Equivalent or CBTE) and showed that although the numbers of patients that were treated in our department each day remained quite stable, there were wide fluctuations in workload when complexity was also considered. A new measure of chemotherapy workload has therefore been proposed.

Conclusion: It is better to measure outpatient chemotherapy throughput with a measure that considers complexity. Complexity of treatment has a significant effect on the productivity of a department. Our CBTE complexity model indicates that patient bookings for chemotherapy need to consider the complexity weighting of the treatment regimen to ensure an even workload distribution. A larger multi-institutional study is proposed that will provide more representative data of treatment times.

849 POSTER

Evidence-based clinical research: integrating the best research evidence with clinical expertise provides alternative interpretations of the effects of immunotherapy in renal cell cancer

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Purpose: The purpose of this study is to critically appraise the available evidence supporting somatic effects (treatment with interferon alpha) or psychosocial effects ("knowledge framing") as causal principle which prolongs survival in patients with advanced renal cell cancer (RCC).

Method: Critical appraisal of the published results of our meta-analysis on immunotherapy of RCC which includes 98 randomized controlled trials (Cochrane review 3/2000) and concludes that interferon alpha causes a marginal (2.6 months) but significant extension of survival.

Results: A more detailed re-interpretation of data suggests that psychosocial rather than somatic effects may cause the observed result. 1. Significant differences in the remission rates and death rates were observed in RCC when immunotherapy (interferon alpha) was compared with a non-immunotherapy as control. 2. There was no relationship between dose and effect. 3. The comparison between interferon alpha and other immuno-therapies demonstrated no significant differences. Higher remission rates were always achieved by immunotherapy (independent of the specificity) than by non-immunotherapies. 4. A placebo-controlled study did not demonstrate superiority of immunotherapy.

Conclusions: The most plausible explanation for the results discussed here is that a harmonious conversation between patient and doctor, the conveyance of trust and hope, and the development of a life perspective influence the results of clinical trials. We call this effect "knowledge framing"; to express that our implicit and explicit knowledge about the illness and potential effects of treatment is part of the physical and biochemical network. We assume that the effects of "knowledge framing"and of placebo are identical but not the under-lying concepts. Differences in the concepts of placebo (P) and of "knowledge framing (K)": 1.The P effect is considered to be an "as if" effect or an illu-sion with a negative attribute. K is considered as a positive and desirable com-ponent of every intervention. 2. The P effect is an unspecific component of a specific pharmacological effect. K is a specific effect based on the information provided. 3. The P effect is conceptionally below the threshold of relevant therapeutic effects, the K effect is not. 4. The application of the P effect is limited to clinical trails, the K effect is an essential part of patient care and is intuitively employed by experienced physicians.

Economical aspects

850 POSTER

Psychological reactions among women with high risk of breast cancer considering prophylactic mastectomy

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Purpose: To describe psychological reactions in a consecutive sample of women with hereditary risk for breast cancer considering prophylactic mastectiomy (PM) and compare them with reference values from the Swedish population. Reasons for considering PM and expectations on the preventive procedure will also be presented.

Patients: Between March 1997 and February 2001, 52 consecutive women with hereditary risk for breast cancer of whom 13 had breast cancer.

Methods: Before deciding on PM, the women were interviewed by a psychologist and responded to questionnaires concerning reasons for considering PM, expectations on PM, anxiety and depressive symptoms (HAD) health related quality of life (SF-36), sexual activity and risk perception.

Results: 24 women expected their life to change positively and 4 negatively after PM. The main reasons for PM was to decrease the risk of breast cancer and early death, and to avoid cancer treatment and breast cancer worries. There were no statistically significant differences between the studied group and reference data from Swedish women on the HAD subscales or on SF-36, with two exceptions. Women with breast cancer scored lower on bodily pain, whereas women with risk but no cancer scored higher than the reference sample on physical functioning.

Conclusion: The studied sample was similar to women in the Swedish population with respect to levels of anxiety, depressive symptoms and HRQOL. Main reasons for PM was to avoid early death in breast cancer.

851 POSTER

Cost-effectiveness analysis of irinotecan+5FU/FA versus oxaliplatin+5FU/FA first-line therapy in advanced colorectal cancer in the UK

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Background: In the UK irinotecan+5FU/FA and oxaliplatin+5FU/FA are licensed treatment regimens for the treatment of metastatic colorectal cancer in the first line setting. However, no studies to date have provided a head-to-head comparison of efficacy and cost effectiveness of these two treatments.

Objective: This study aims to estimate the cost-effectiveness of irinotecan+5FU/FA versus oxaliplatin+5FU/FA in the first line treatment of advanced metastatic colorectal cancer from the perspective of the UK National Health Service.

Methods: A decision tree model tracks patients through the course of their disease and estimates average survival and associated costs. A systematic review and meta analysis were undertaken for irinotecan and oxaliplatin to provide data on response rate, time to progression, survival rates (median survival 67.5 weeks versus 55 weeks), drop out from toxicities, and major adverse events. Given that there are no significant survival advantage shown in the trials for oxaliplatin it was assumed that the median survival for oxaliplatin would be equivalent to that observed for 5FU/FA in patient populations similar to those of the trials for irinotecan. Medication costs were based on the British National Formulary and allow for wastage. Resource utilization for routine treatment and monitoring, adverse event management and other clinical parameters was elicited from a survey of five UK oncologists with extensive experience with the therapies. Wherever

possible, acquisition costs from published sources were applied to the resource use identified for events.

Results: The total costs including drug cost, treatment administration, management of toxicity and of disease progression amounted to £16,701 per patient treated with irinotecan+5FU/FA and £16,009 per patient treated with oxaliplatin+FU/FA. When the difference in cost is related to the clinical benefit of irinotecan, the cost per life year gained amounted to just £2,881. Varying the survival difference for oxaliplatin showed that the cost per life year gained would not rise above £20,000 unless there was a significant survival difference for oxaliplatin over 5FU/FA.

Conclusion: In the treatment of advanced metastatic colorectal cancer in the UK, irinotecan+5FU/FA can be considered to cost-effective versus oxaliplatin+5FU/FA

852 POSTER

Economic evaluation of the clinical management of lung cancer in France

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Rationale: The costs of lung cancer care are unknwon in southern european countries, like France. The objective of this study was to assess the overall costs per lung cancer patient.

Setting: A representative sample of institutions in which lung cancer are treated (3 teaching hospitals, 3 public hospitals, 3 private clinics and 2 cancer treatment centers).

Methods: The perspective of the economic study was the payer (French National Insurer). A retrospective study was performed in patients admitted in the selected institutions (from 1998 July, 1st to 1999 June, 30th). Only direct costs were recorded. All the variable direct costs (chemotherapy, radiotherapy, surgery, drugs, hospitalizations, transports) were recorded from the diagnosis to the terminal care or the date of censorus (2000 January, 1st) for each patient. The fixed direct costs were extracted from the french national cost scale for public hospitals and private clinics. Six Markov models were built: extensive SCLC, limited SCLC, surgical NSCLC, non surgical stage I, II NSCLC, stage III NSCLC and metastatic NSCLC. Parameters for the models were estimated from collected data, practical guidelines for lung cancer in France and experts opinions. Markov models were run with a three months interval. The costs were introduced in each time interval. Monte-Carlo simulations were performed to analyse the validity of the results (sensivity analyses) and calculate the 95% confidence interval at 1 and 2 years.

Results: 430 patients were included during the study, according to the epidemiology of lung cancer (79% NSCLC and 21% SCLC). The results are as follows:

Lung cancer (average costs 1999 euros)

	1 year	95% CI	2 years	95% CI
LC	22 073	(5 351-36 423)	25 472	(7 426-48 179)
SCLC	22 633	(10 557-37 508)	24 337	(10 557- 37 508)
NSCLC	21 822	(6 061-36 718)	25 903	(7 693-49 331)

During the first year of care, diagnosis corresponded to 11 to 17%, initial treatment 37 to 70%, adverse events 5 to 17%, relapse 0,5 to 4,5%, terminal care 6 to 18%, transports 6 to 11% according to the histology and stages of the diseases.

Conclusion: These are the first results on the costs of lung cancer in France. Analyses of treatment strategies and comparison of cost-effectiveness results are on going. Complete results for the 6 models will be presented at the meeting.

Supported by a grant from Aventis pharmaceuticals (France)

853 POSTER

A stochastic economic evaluation of Letrozole versus Tamoxifen as a first-line therapy for postmenopausal women with advanced breast cancer

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Letrozole is a new generation aromatase inhibitor that is a feasible alternative to tamoxifen as the preferred choice of first-line hormonal therapy for patients with advanced breast cancer. This paper presents the results of an economic evaluation comparing letrozole and tamoxifen as a first-line hormonal therapy in postmenopausal women diagnosed with advanced breast cancer. A Markov process was built to describe possible patient pathways from the point of diagnosis, which was populated using patient-specific clinical trial data, data from the existing literature, and expert opinion. Probability distributions were specified for the majority of the input parameters, which represented the uncertainty about their true value. This facilitated the stochastic analysis of the decision model, whereby distributions of the model's outputs (aggregate costs and lifeyears) were estimated that enabled the statistical analysis of the cost-effectiveness results. The baseline results show that letrozole is an extremely cost-effective alternative to tamoxifen as a first-line hormonal therapy with a mean incremental cost per life year gained of £500. Even under the most severe assumptions the incremental cost increases to £12,530, which remains a relatively low cost to pay to gain an additional life year.

854 POSTER

Mapping clinical cancer research by MEDLINE publications in the years 1995-1999

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In this study, we address the geography of clinical cancer research in the years 1995-1999.

A MEDLINE search (http://www.ncbi.nlm.nih.gov) was performed to retrieve scientific papers in clinical oncology reporting phase I, phase II, and phase III studies. The following search strings were used: cancer AND chemotherapy AND phase I [TITL] OR dose finding [TITL]cancer AND chemotherapy AND phase II [TITL]cancer AND chemotherapy AND phase III [TITL] OR randomised [TITL] OR randomized [TITL]. The retrieval was limited to papers published from January 1, 1995 to December 31, 1999. Only studies reporting antiblastic chemotherapy have been considered, either alone or in combination with radiotherapy, surgery, immunotherapy. The country was assigned according to the address field in the MEDLINE record. For each country, the total number of published papers, the total impact factor (IF), and the mean IF were determined. Similar calculations were performed to compare the European Union vs. North America. The performance of cooperative groups was also evaluated. The attribution of a publication to a group was determined according to the mention of the group in the paper title.

3,247 papers were identified which report phase I, phase II, or phase III clinical trials in oncology and have been published between 1995 and 1999. Here, we consider the 25 countries which score at least ten records matching our search strings published in the years 1995-1999. These 25 countries account for 2,818 papers, corresponding to 87% of the retrieved papers. The United States ranks first by number of published papers, accounting for 35.5% of the world's papers. Italy is second (8.9% share), followed by the United Kingdom (6.6%), and France (5.9%). Investigators at North American Institutions published a higher number of papers compared to their European colleagues (1,242 vs. 1,254). Moreover, the mean I.F. of North American papers is higher than the papers with a European address (3.55 vs. 3.18). Interestigly, the majority of phase I studies were performed in North America, while most of phase III studies were performed in Europe. EORTC is the most active cooperative group.

Taken together, these results provide information on the geography of clinical cancer research worldwide, which may reflect the human and economic resources involved in this field.

855 POSTER

Therapeutic strategies and costs for patients with head and neck squamous cell carcinoma

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Objective: To describe the therapeutic strategies that are currently applied in treating Head and Neck Squamous Cell Carcinoma (HNSCC) in France and to estimate their costs.

Methods: A retrospective patient charts review was conducted in 82 hospitals spread all over France and representative of the different types of centres treating HNSCC. Patients were classified into 4 groups: patients with resected primary tumors (P-RES; N = 107), patients whose primary tumor was not resected (P-NR; N = 111), patients with locoregional recurrence only