patients are at home. The aim of the present RCT was to assess the effectiveness of a home care nursing programme compared with standard care in the management of treatment toxicities, anxiety, depression and quality of life in colorectal and breast cancer patients receiving oral capecitabine (Xeloda®).
Standard care involved patient education at hospital and medication for common toxicities. The home care programme additionally consisted of a home care nurse visit during the first week of chemotherapy, which provided patients with education about symptoms and their management. Weekly phone calls assessed and monitored symptoms, and provided emotional support and reassurance. Patients were assessed using weekly CTC toxicity scales, with anxiety, depression and quality of life scales administered every 6 weeks. Patients were followed up for 18 weeks (6 cycles). In this trial, 164 patients were randomised to receive either home care nursing (n = 83) or standard care (n = 81).
Results: Patients in the home care arm experienced significantly lower symptoms (composite score of all symptoms). More specifically, the had lower oral mucositis (P = 0.003), diarrhoea (P = 0.008), constipation (P = 0.008), nausea (P = 0.003), vomiting (P = 0.041), pain (P = 0.003), fatigue (P = 0.018) and insomnia (P < 0.0005), the majority of symptoms maintaining the improvement over the 6 cycles. There were also trends towards lower anxiety and indications of less service utilization in the home care group. No difference between the two groups was seen for hand-and-foot syndrome, quality of life and depression.
Conclusions: A nursing symptom management regimen-focused home care programme was able to better assist patients in managing treatment-related toxicities and support them during the treatment period than receiving standard care alone.

290 INVITED

Cancer supportive care – creating opportunities within the DRG-system

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Treating cancer patients combines different professions and numerous transitions between in-patient and outpatient care settings. Awareness and continuity of supportive care are needed to improve the quality of the patients treatment experience and also clinical outcomes.
In this paper, first the reimbursement of supportive cancer care in the German DRG system in inpatient settings is analysed. Reimbursement opportunities and shortcomings are identified. In the second part, the traditional system is contrasted with the ongoing development of so-called flat fees for complex treatments ("*Komplexpauschale*") covering treatment both in ambulatory and in-patient care on a contractual basis between hopitals and ambulatory providers. For cancer care, so far a palliative care flat fee has been introduced allowing the reimbursment of integrated care contracts – these reimbursement rules are analysed towards their capacity to fulfill the need of cancer patients regarding access to and amount of supportive care offered as well as the capacity for guaranteeing continuity of care.
In the next part, the German developments on sector transcending flat reimbursment fees are contrasted with the international debate on evidence-based case rates and performance oriented multiple-sector reimbursement rates in cancer care. Problems and challenges remain when it comes to integrate an adequate level of supportive care into a system characterized by increasing economic pressures through flat fee reimbursements. With ever-increasing demands on nursing and medical care of cancer patients, the discussion of the role of specialized cancer nurses in providing supportive care in the German setting concludes the paper.

Special Session (Wed, 23 Sep, 17:00−18:00)
Circulating tumour cells

292 INVITED

Methods for detection of circulating tumour cells: potential & limitations

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Metastasis is the main cause of death in patients with solid epithelial tumours (i.e. carcinomas), which represent the majority of cancers in industrialized countries.
Extremely sensitive immunocytochemical and molecular assays are required to allow the unambiguous identification and characterization of single circulating tumor cells (CTC) in the peripheral blood and disseminated tumor cells (DTC) in the bone marrow (BM) as a common and easily accessible homing organ for cells released by epithelial tumors of various origins. Detection methods are usually used in combination with tumor cell enrichment procedures, including density gradient centrifugation (Ficoll-Hypaque separation), immunomagnetic procedures or size filtration methods to enrich tumor cells prior to their detection.
These enrichment and detection methods currently used for the detection of CTC/DTC will be reviewed with their potential and limitations.

293 INVITED

Characterisation and monitoring of circulating tumour cells

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Early spread of tumor cells is usually undetected by current imaging technologies. Therefore, in patients with cancer and no signs of overt metastases, sensitive methods have been developed to detect circulating tumor cells (CTC) in the peripheral blood and disseminated tumour cells (DTC) in the bone marrow. These technologies can be classified into cytometric and/or immunological and molecular approaches. Interestingly, the bone marrow seems to be a common homing organ for cells derived from various epithelial tumors, and level 1a data from European and US groups have sustained the prognostic impact of DTC in the BM of breast cancer patients. Sequential peripheral blood analyses, however, are more convenient for patients than BM analyses in patients with solid tumours and many research groups are currently assessing the clinical utility of CTC for assessment of prognosis and monitoring of systemic therapy. In view of the plethora of prognostic indicators – especially in breast cancer – monitoring of CTC during and after systemic adjuvant therapy might provide unique information for the clinical management of the individual cancer patient and allow an early change in therapy years before the appearance of overt metastases signals incurability. There is an urgent need for biomarkers for real-time monitoring of the efficacy of systemic adjuvant therapy in individual patients. At present, the success or failure of anti-cancer therapies is only assessed retrospectively by the absence or presence of overt metastases during the post-operative follow-up period. However, overt metastases are, in general, incurable by most current therapies. The monitoring of CTC will provide new insights into the selection of tumor cells under biological therapies. Molecular characterization of DTC and CTC opens a new avenue for understanding early metastatic spread of tumour cells and might contribute to the identification of metastatic stem cells with important implications for future therapies.

294 INVITED

Detection and characterization of tumour cells in sentinel lymph nodes and bone marrow of patients with breast cancer

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The sensitivity and accuracy of methods for tumour cell detection in sentinel lymph nodes and bone marrow from breast cancer patients is debatable. In a large collaborative study on samples obtained at time of primary surgery we have examined the presence of tumour cells by immunobead selection (IMS) and characterization, in many cases followed by molecular studies on a pure population of cancer cells specifically isolated by the CellPick system (MMI). The sentinel lymph nodes were cut in half, one half was disaggregated and used for IMS with an anti-EpCam antibody, and the other half for immunohistochemical (IHC) identification with an anti-cytokeratin antibody applied to ten sections of each node. The IMS method showed by far the highest sensitivity, but there was only a minimal overlap in results between the two methods. Verification of the cells identified with IMS as tumour cells was obtained by simultaneous binding of non-magnetic fluorescent beads coated with antibodies recognizing known breast cancer markers (Muc1, erbB2, EGFR, B7-H3). Surprisingly, such validated tumour cell positive samples were equally distributed between the IHC positive and negative groups. The results suggest important methodological problems inherent to both IMS and IHC detection approaches. To further investigate this, we used qRT-PCR and arrayCGH on the IMS selected cells followed by specific isolation of 5−20 bead-confirmed tumour cells. qRT-PCR targeting mammaglobin, AGR2, TFF1, and SBEM mRNA were positive with at least one marker in 50% of 60 IMS EpCam positive samples studied, but was negative in cells isolated from bone marrow. ArrayCGH

showed amplification or deletions in many but not all lymph node samples. Surprisingly, one IMS EpCam positive sample that was negative for all other markers, and also by IHC, showed distinct amplifications and deletions proving the malignant nature of the cells. Together the results suggest the existence of heterogenic micrometastatic tumor cell populations with a complex gene and protein expression pattern, including differences between cells obtained from different. The data raises questions on the accuracy of the methods used for identification of micrometastatic tumour cells, and also suggest the presence of tumour cells in the two tissue types without the capacity to give rise to relapse.

Special Session (Wed, 23 Sep, 17:00−18:00)
Case-based: leadership and management

295 INVITED

Measuring quality at a local level

D. Doran[1]. [1]*Lawrence Bloomberg Faculty of Nursing -, Nursing, Toronto, Canada*

Background: At no time in the history of health care has the growth in knowledge and technologies been so profound. However despite rapid advances in science and technology, the health care system has struggled in its ability to provide consistently high-quality care to all who require health care services.
Purpose: This paper explores how we can utilize quality measurement at the local level to transform care at the bedside. It embraces the vision set out in the United Kingdom National Health System Next Stage Review report that quality improvement should be the organising principle of everything we do. The local level refers to the unit of care such as a hospital unit, team, patient care programme, or community centre.
Methodology: The paper draws on the health care quality literature and the results of three studies to discuss approaches to local quality measurement and strategies for the continuous improvement of patient care. The three studies utilized quasi-experimental research designs to evaluate the feasibility and impact of providing clinicians with access to real-time feedback about patient outcomes data along with access to research evidence to support the continuous improvement of patient care.
Results: High quality care is conceptualized as having three dimensions: (1) ensuring that care is safe, (2) effective, and (3) provides patients with the most positive experience possible. All staff must be active participants and leaders in transforming the quality of care. Providing clinicians with access to real-time feedback about quality indicators along with access to research evidence promotes reflective practice and encourages the uptake of evidence-based practice guidelines. However in order to promote effective utilization of local quality measurements it is important to create a favourable context for evidence-based practice.
Conclusion: It is recommended that we provide clinicians with access to quality measurement indicator data in real time along with access to information resources to support the continuous improvement of patient-centred care.

296 INVITED

Encouraging innovation in clinical practice

M. Krishnasamy[1]. [1]*Peter MacCallum Cancer Centre, Department of Nursing and Supportive Care Research, Melbourne Victoria, Australia*

This paper will present an overview of essential components of innovative health care. Consideration will be given to the characteristics of inspiring health care teams and to the features of novel systems of health care. The audience will be invited to think about how these characteristics and philosophies can be assimilated into clinical practice in order to optimise patient-reported outcomes. The benefits of innovative clinical practice as a means of practice advancement for the individual practitioner will also be explored. Two practice models currently in place at the Peter MacCallum Cancer Centre in Melbourne, Australia, will be presented as pragmatic examples of how innovations in practice can be achieved through utilising the skills and expertise of the multidisciplinary team.

Thursday 24 September 2009

Scientific Symposium (Thu, 24 Sep, 09:00−11:00)
Optimising therapy of young women with early breast cancer

297 INVITED

Epidemiology and prognosis of breast cancer in very young population

P. Tai[1]. [1]*University of Saskatchewan, Department of Oncology Allan Blair Cancer Center, Regina, Canada*

Background: Very young women aged less than 35 with breast cancer are regarded as high-risk patients in the literature. This study examines the relationship between age and mortality for breast cancer patients. This may have important prognostic and therapeutic implications.
Material and Methods: Data of 83,804 pT1−2M0 patients from 9 registries of the Surveillance, Epidemiology, and End Results Program (SEER) of the United States were used. This study employed proportional hazards to model mortality in women with T1−2 breast cancers. The martingale residuals of the model were used to examine the effect of age on mortality. This procedure was applied to node-negative (N0) and node-positive (N+) patients. All causes mortality and breast cancer specific mortality were evaluated. The analysis was applied first to node-negative cases ("training set") in order to find an expression of the functional form which relates age to mortality. The functional form obtained from node-negative cases was then applied to node-positive cases ("validation set"). In addition to the validation with the same transformation which was obtained for node-negative patients, a further iterative search was performed in order to improve the fit for node-positive patients. We also studied the German Breast Cancer Study Group GBSG-2 dataset, a separate prospective database of 686 node-positive patients.
Results: The relationship between age and mortality is biphasic. This results in a U-shaped curve. For both N0 and N+ patients among the T1−2 group, the analysis suggested two age components. One component is linear and corresponds to a natural increase of mortality with each year of age. The other component is quasi-quadratic and is centered around age 50. This component contributes to an increased risk of mortality as age departs from 50. It suggests a hormonally related process: the farther from menopause in either direction, the more prognosis is adversely influenced by the quasi-quadratic component. Younger patients experience the same relative mortality risk from all causes as do older patients. A 30-year old patient has a risk of death almost equal to a 60-year old patient.
There is a complex relationship between hormone receptor status and other prognostic factors, like age. Very young patients tend to develop hormone receptor negative tumors. They have poorer survival explained in part by presentation with later stage disease and more aggressive tumors, in terms of grade and receptor status. They are more likely treated with conservative surgery than older patients.
The German Breast Cancer Study Group GBSG-2 dataset showed similar findings, confirming the poor prognosis of very young breast cancer patients.
Conclusions: The present analysis confirms the findings of many epidemiological and clinical trials that the relationship between age and mortality is biphasic. Compared with older patients, young women experience an abnormally high risk of death. These facts are important in the discussion of options for adjuvant treatment with breast cancer patients.

298 INVITED

Adjuvant therapy of very young women with early breast cancer

O. Pagani[1]. [1]*Oncology Institute of Southern Switzerland, Division of Research, Bellinzona, Switzerland*

Approximately 7% of women with breast cancer (BC) are diagnosed before the age of 40 years, and this disease accounts for more than 40% of all cancer in women in this age group.
Women under 35 or 40 with primary BC have historically been considered at poor prognosis, independently of other factors, but in some recent studies age is not independent in multivariate analyses, which include gene signatures.
Treatment choices on the contrary are dependent on BC biology (receptor status) as well as patient factors (ovarian function and desire for future fertility).
Trial results of adjuvant treatments for premenopausal women largely reflect outcomes for patients in their 40 s. Thus, findings from studies that consider these average results may not be directly applicable to younger patients.